IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE,

Plaintiff,

v.

CENTERS FOR DISEASE CONTROL AND PREVENTION, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Civil Action No. 2:23-CV-00102-Z

APPENDIX IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Respectfully submitted,

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CERTIFICATE OF SERVICE

On November 24, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Sarah E. Delaney
Sarah E. Delaney
Assistant United States Attorney

UNITED STATES DISTRICT COURT FOR NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, *Plaintiff*, v. CENTERS FOR DISEASE CONTROL AND PREVENTION, *et al.*, *Defendants*.	)	Civil Action No. 2:23-cv-00102-Z

DECLARATION OF ROGER ANDOH

I, Roger Andoh, declare the following to be true and correct:

1. I am the Freedom of Information Act ("FOIA") Officer for the Centers for Disease Control and Prevention ("CDC") and the Agency for Toxic Substances and Disease Registry ("ATSDR"), agencies within the U.S. Department of Health and Human Services ("HHS"). I have held this position since June 2016. In this capacity, I am responsible for supervising and directing the day-to-day activities of the CDC/ATSDR FOIA Office ("FOIA Office"), which is responsible for responding to requests under FOIA, 5 U.S.C. § 552, for records from within all CDC and ATSDR operating divisions.

2. My official duties include, *inter alia*, (i) supervising searches conducted by the FOIA Office for records potentially responsive to a FOIA request, including coordinating with CDC and/or ATSDR components that are likely to possess such records; (ii) determining whether the records collected during a search are responsive to the FOIA request; and (iii) determining whether responsive records are appropriate for release and whether any responsive records should

be withheld, either in whole or in part, in accordance with FOIA and HHS's regulations, *see* 45 C.F.R. Part 5.

3. I make the statements in this declaration on the basis of personal knowledge and on information acquired by me in the course of my official duties, including my familiarity with the FOIA Office's resources and procedures for responding to FOIA requests, my review of and determinations regarding the FOIA request that is the subject of this litigation, and my discussions with CDC and HHS personnel who are knowledgeable about the records requested by the request.

4. The purpose of this declaration is to explain the basis for my determination that certain information should be withheld pursuant to FOIA's Exemption 6, 5 U.S.C. § 552(b)(6), and cannot be reasonably segregated.

I. Plaintiff's FOIA Request

5. The CDC FOIA Office received a FOIA request from Plaintiff Freedom Coalition of Doctors for Choice on January 3, 2023, that sought the following categories of agency records: "*All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*" Appended to the FOIA request was a request for expedited processing under the agency's regulations. The document attached as Exhibit A is a true and correct copy of that letter.

6. On January 4, 2023, I sent a letter to Christopher Wiest (who submitted the FOIA request on behalf of Plaintiff), acknowledging receipt of Plaintiff's FOIA request, assigning it request number 23-00462-FOIA, and denying Plaintiff's requests for expedited processing and fee waiver. The document attached as Exhibit B is a true and correct copy of that letter.

7. On January 12, 2023, I sent a letter to Mr. Wiest setting forth the agency's final

determination under 5 U.S.C. § 552(a)(6)(A) regarding Plaintiff's FOIA request and producing all responsive, non-exempt records. The document attached as Exhibit C is a true and correct copy of that letter.

8. On January 13, 2023, Plaintiff filed an appeal of CDC's final determination regarding Plaintiff's FOIA request to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services. On January 17, 2023, the Office of the Secretary's Freedom of Information Act Office ("OS FOIA") acknowledged receipt of Plaintiff's appeal. On July 5, 2023, the OS FOIA Office informed Plaintiff that in accordance with 45 CFR Part 5, due to the commencement of the lawsuit, Plaintiff's appeal was administratively closed. These documents attached as Exhibits D, E, and F are true and correct copies of those letters.

9. On March 31, 2023, Plaintiff filed an appeal of CDC's determination regarding Plaintiff's request for a few waiver to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services. On April 12, 2023, the OS FOIA Office informed Plaintiff that the appeal letter was received on April 3, 2023, and was administratively closed as moot, since no fees arose from the request. This April 12, 2023 notice was re-sent to Plaintiff on July 3, 2023, as the email address provided by Plaintiff, which was used to send the April 12, 2023 letter, did not allow the April 12, 2023 message to be delivered. These documents attached as Exhibits G, H, I, and J are true and correct copies of those letters and email notice.

II. CDC's Processing of Plaintiff's Request

10. V-safe is an active vaccine-safety surveillance program that monitors the health of voluntary participants following COVID-19 vaccination. V-safe employs a smartphone-based

application that allows participants who received a COVID-19 vaccine dose to report their health after vaccination in daily, weekly, and monthly intervals. Enrollment in V-safe is voluntary and is initiated by the participant (or, if a dependent, his or her representative) by accessing vsafe.cdc.gov. A participant enrolls in V-safe by entering basic personal information (*e.g.*, name, mobile number, date of birth, sex, zip code) and the vaccine dose(s) he or she has received. V-safe participants are informed prior to enrollment (as well as each time they log into their accounts) that "the confidentiality, integrity, and privacy" of their personal information in V-safe will be safeguarded.[1] Once a participant is enrolled, the smartphone application will periodically send text messages to the participant with individualized links that direct him or her to web-based health check-in surveys. The V-safe smartphone application will ask participants to complete a health check-in survey (i) every day for the first week following vaccination; (ii) every week for the next five weeks; and (iii) at three, six, and twelve months after vaccination.[2] The health check-in surveys ask participants a series of questions with pre-specified answer options—*e.g.*, a list of symptoms to select to answer "*Have you experienced any of these symptoms today?*"—as well as questions that allow a participant to enter a "free text" response, as explained further below.[3]

11. All data that a V-safe participant submits to the V-safe smartphone application is initially collected and stored in a secure server maintained by Oracle, a software company,

[1] *See* vsafe.cdc.gov. CDC's website also includes a V-safe "Frequently Asked Questions" page, which states that participants' "personal information in v-safe is protected so that it stays confidential and private." *See* CDC, *Frequently Asked Questions and Troubleshooting*, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/faqs.html.

[2] If and when a participant logs another dose (whether from the primary series or a booster dose) into his or her V-safe smartphone application account, a new round of health check-in surveys starts and follows the same time intervals as the initial round.

[3] Since December 14, 2020, CDC has collected information from over 10.1 million V-safe participants.

pursuant to a contract with HHS.[4] To obtain the data stored on Oracle's server, staff on the V-safe Safety Team download data files from Oracle's secure FedRAMP-approved cloud location onto a secure server that CDC maintains. These daily data files are downloaded and maintained in comma-separated value ("CSV") format. Each workday, the V-safe Safety Team downloads the following files of data newly submitted to the V-safe smartphone application: (i) participant registration information; (ii) participant vaccination information; (iii) answers to health check-in surveys for participants 3 years and older; (iv) answers to health check-in surveys for participants younger than 3 years; and (v) participant race/ethnicity information. Then, each Monday morning, the prior week's data files are added to the corresponding files containing the cumulative data that CDC has collected through the V-safe smartphone application since its inception (*e.g.*, the daily files of "participant race/ethnicity" data are added to the file containing the cumulative "participant race/ethnicity" data). These cumulative data files are maintained in both CSV and statistical analysis software ("SAS") formats. Once they are added to the cumulative data files, the daily data files are archived on CDC's secure server. Only a small group of CDC personnel (all of whom work on the V-safe Safety Team) has authorization to access the daily and the cumulative data files.

12. CDC has also publicly released a sizable amount of the data collected through the V-safe smartphone application (excluding information typed into the free-form responses fields as explained in greater detail below). This data was provided to Plaintiff on January 12, 2023, via a publicly available website: https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d. This publicly released data includes the registrant codes for all V-safe participants.

[4] The server is housed in the Oracle Cloud Infrastructure U.S. Government Cloud and is Federal Risk and Authorization Management Program ("FedRAMP") approved.

13. Based on this information, I determined that there were only two likely locations of records responsive to Plaintiff's FOIA request. The first location, as to Plaintiff's request for the data from the free text response fields, was located within CDC's National Center for Emerging and Zoonotic Infectious Diseases and was controlled solely by a team of CDC staff responsible for administering the CDC's "V-safe" program ("V-safe Safety Team"). The second location, as to Plaintiff's request for the registrant codes for V-safe participants, was located online at https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d, as part of the V-safe data previously made publicly available.

14. On January 12, 2023, the FOIA Office produced to Plaintiff a link to download a copy of the public V-safe data released by CDC, which as explained above, also contains the registrant codes for all V-safe participants. The datasets in the public V-safe data are labeled as "consolidated_health_checkin," "consolidated_race_ethnicity," "consolidated_vaccinations," and "consolidated_registrants." Additionally, Plaintiff was provided the "v-safe motivation survey" data.

15. For the reasons set forth below, I determined that V-safe participants' free-text responses found in the cumulative data files for participant answers to V-safe's health check-in surveys ("Free-Text Responses") should be withheld under Exemption 6, and that the non-exempt information contained in the free-text responses was not reasonably segregable.

III. CDC's Determination that V-safe Participants' Free-Text Responses to Health Check-in Survey Questions Should be Withheld in Full Pursuant to Exemption 6

A. The Free-Text Responses

15. The cumulative data files for participant answers to V-safe's health check-in surveys ("Health Check-in Surveys Data Files") include 7.8 million Free-Text Responses submitted by participants between December 14, 2020, and December 31, 2022.

16. Each health check-in survey that a V-safe participant received during this period contained several questions that allowed the participant to type a free-form response into a text field (as opposed to selecting a pre-specified answer option). These Free-text Response fields were included in the surveys to provide V-safe participants with an opportunity to report other symptoms or health events not specified in checkboxes on daily surveys, as well as new or worsening symptoms or health events on weekly surveys. If a V-safe participant indicated on any survey that medical care was received for the symptoms reported, the V-safe Call Center followed-up with the V-safe participant to assist with reporting this medical event. The V-safe health check-in surveys included three Free-text Response fields:

a. All health check-in surveys asked the participant whether any reported symptoms or health conditions caused the participant to "*Get care from a doctor or healthcare professional.*" If the participant answered "yes" to this question, the survey then asked the participant to identify the type of healthcare visit by either choosing from a list of pre-specified answer options or to describe the visit in a free-text field marked as "other."

b. The daily health check-in surveys during the first week after vaccination asked the participant to select from a list of pre-specified options of symptoms that he or she was experiencing, and also asked the participant to describe in a free-text field "*Any other symptoms or health conditions you want to report.*"

c. Each health check-in survey after the first week asked the participant to provide a description of their symptom(s) in a free-text field if they answered yes to the following question: "*Since your/their last check-in, have you/they experienced any new or worsening symptoms or health conditions?*"

17. Although CDC had intended that the free-text fields within the V-safe health check-in surveys capture no more than 250 characters per question, quality assessments of the health check-in data conducted by the V-safe Safety Team revealed that two free-text fields were inadvertently designed to collect up to 4000 characters per response. This allowed participants to submit much lengthier free-text responses to the question "*Any other symptoms or health conditions you want to report*" and the question regarding the type of healthcare a participant received. These free-text fields were modified in June 2021 to capture a maximum of 250 characters for all future surveys.

18. Early quality assessments of the health check-in data conducted by the V-safe Safety Team revealed repeated instances of V-safe participants providing personally identifying information ("PII") in their free-text responses. These responses included, *e.g.*, full names, last names, full dates of birth, full or partial residential addresses, telephone numbers, e-mail addresses, social security numbers, and dates of death.

19. The FOIA Office has since examined a random sample of 500 Free-Text Responses within the Health Check-in Surveys Data Files.[5] The examination of that random sample revealed that over 7% of the Free-Text Responses in this sample contained some form of PII, such as full names, dates of birth, social security numbers, and telephone numbers. In addition, I conducted a separate random search of 500,000 Free-Text Responses to determine the type of PII found within these responses, using a cursory keyword search of terms that would likely reveal PII, such as "@gmail.com," "@yahoo.com," "mobile number," "cell," "name," and "phone." The following are just some examples of PII found within those Free-Text Responses, organized by participants' unique registrant codes:

[5] This sample was taken by arbitrarily selecting Free-Text Responses at random from a sample of 500,000 Free-Text Responses to which the FOIA Office was provided short-term access by the V-safe Safety Team.

- H74880: Full name, date of birth, telephone number, home address, email address
- H206854: Telephone number and email address (reflecting participant's full name)
- H513330: Full name, date of birth, telephone number, home address, email address
- H255454: Full name, cell phone number, email address
- F449322: Phone number and email address
- H187122: Old and new telephone numbers
- F371256: Full name and deceased child's name
- F434361: Full name and telephone number
- G59766: Full name
- H227312: Email address

20. Based on these random samples and searches, as well as the V-safe Safety Team's familiarity with the data files, it is likely that many of the Free-Text Responses contain the same or similar forms of PII, and therefore a manual review of all 7.8 million fields is required. Because the Free-Text Responses contain V-safe participants' PII, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy by publicly connecting those individuals to their private and highly sensitive health information, I determined that the Health Check-in Surveys Data Files contain information that should be withheld pursuant to FOIA Exemption 6. Therefore, the personal interests in keeping this information private far outweighs the public's interest in disclosure.

21. As explained in further detail below, CDC is already working to make the data available to the public in a format that is both useful for research and ensures that participants' highly sensitive health information is protected. Indeed, it is this robust extrapolated data of any adverse events—not the actual content provided in the Free-Text Responses—that would inform

the public as to government activities. Further, an accidental release of PII from a Free-Text Response would cause irreparable harm to not only the individuals whose information is disclosed, but to the V-safe application program. Even an inadvertent disclosure could cause the public to be hesitant about sharing information and to distrust CDC's ability to safeguard PII, therefore impacting the program's ability to conduct research on vaccine efficacy.

B. Processing the Free-Text Responses Would Unduly Burden the Agency

22. I also determined that the non-exempt information within the Free-Text Responses is not reasonably segregable, because to segregate such information would be unduly burdensome.

23. Processing the Free-Text Responses would require a FOIA analyst conducting a manual, line-by-line review of each response to determine whether any information is PII or otherwise exempt from disclosure under Exemption 6, and to redact any exempt information by replacing it with "(b)(6)" while ensuring that any non-exempt portions of the response are segregated. This process will likely require that the FOIA analyst conduct time-consuming research to determine whether the disclosure of certain types of information will cause an interference with personal privacy.

24. After the FOIA analyst completed his or her review and redaction of the 7.8 million Free-Text Responses, either a senior FOIA analyst or a Team Lead in the FOIA Office would have to conduct, pursuant to FOIA Office procedures, another manual, line-by-line review of each Free-Text Response (both the redacted and the unredacted version) to ensure accuracy, consistency, compliance with agency standards and processes, and redaction of all PII and other information that should be withheld pursuant to Exemption 6.

25. I estimate that, on average, a FOIA analyst devoted only to processing the Free-Text Responses will be able to process about 2,525 responses per 40-hour week. I based this

estimate on the amount of time it took a FOIA analyst to finish processing a similar document, such as the free-text entries from the V-safe motivation survey data that Plaintiff mentions in the Complaint, as well as my years of experience supervising the processing of records under FOIA. Although processing these Free-Text Responses might be similar to processing the V-safe motivation survey free-text entries, I would like to point out that Plaintiff's assumption of equating the type of information solicited and the character length of the free-text fields in the motivational survey to that of the V-safe application is inaccurate. Additionally, as stated above, there was an inadvertent design error in the Free-Text Response fields of the V-safe application, which temporarily increased the number of characters that could be collected. Therefore, the responses between these two vary both in character length and in the type of information collected.

26. My estimate also attempts to account for the time it may take a FOIA analyst to conduct research or consult with a subject-matter expert regarding a particular Free-Text Response. And although I estimated that, on average, it will likely take a senior FOIA analyst or a Team Lead less time to review a Free-Text Response after a FOIA analyst has processed it, a second-level reviewer will still need to look at the information that an analyst redacted to ensure that the redaction is proper, and also will need to ensure that no PII remains in any unredacted Free-Text Response. Therefore, at a minimum, I estimated that it would take a FOIA analyst about 123,564 workhours to complete just the first level of processing for the 7.8 million Free-Text Responses within the Health Check-in Surveys Data Files. Further, I estimate that the second level of review by a senior FOIA analyst or Team Lead will likewise take tens of thousands of workhours to finish.

27. Given the enormous volume of the Free-Text Responses and the considerable amount of time it would take for the FOIA Office to review and redact the highly sensitive health

information of hundreds of thousands of V-safe participants, processing these responses would create an extraordinary and undue burden on CDC. As explained above, by its nature, FOIA processing requires human beings to manually analyze records to determine whether information is, based on content and context, exempt or non-exempt from disclosure. Whether CDC has the ability to process the Free-Text Responses thus depends on the ability of human beings to complete the work, and to do so with the necessary level of care given the highly sensitive nature of the information involved.

28. In light of its limited staff and resources, it is not reasonably possible for the FOIA Office to process the Free-Text Responses for production with the necessary PII redactions. The FOIA Office comprises thirteen FOIA analysts who are responsible for responding to all FOIA requests from receipt to completion of administrative appeal, as well as assisting with any related litigation. During fiscal years 2019 through 2022, the FOIA Office processed about 8,719 requests, 412 appeals, and assisted with 24 cases regarding FOIA requests under its purview. These thirteen FOIA analysts must continue to process the requests the FOIA Office received both before and after Plaintiff submitted its request.

29. As explained above, under my best estimate, it will take about 123,564 workhours to complete the FOIA-analyst-level processing of the Free-Text Responses. And if the FOIA Office were to devote all thirteen FOIA analysts to work full-time (*i.e.*, 8 hours per day, 40 hours per week) on processing the Free-Text Responses, it would still take them almost exactly 4.5 years to complete the task. But as just explained, devoting thirteen FOIA analysts—or even half of them—to processing one request is not a viable option, as the FOIA Office cannot put all other requests, appeals, and related litigation tasks on hold for the sake of processing a single dataset in response to a single FOIA request.

C. CDC Committed Resources to Processing Free-Text Responses for Public Use

30. Additionally, processing the Free-Text Responses under FOIA would largely duplicate ongoing efforts by CDC to make the data contained within the file publicly available in a format that is both useful for research and that ensures participants' highly sensitive health information is protected. In September 2022, CDC finalized a contract with an information-technology services company to translate the data collected from V-safe participants' free-text responses to V-safe's health check-in surveys into Medical Dictionary for Regulatory Activities ("MedDRA") terminology or "codes."

31. MedDRA coding is a widely accepted approach to standardizing reports of adverse health events that has been utilized for over a decade by public health officials and regulatory authorities, including CDC and the Food and Drug Administration, to provide a detailed yet standardized understanding of medical diagnoses and symptoms.[6] MedDRA coding facilitates research by converting highly variable language describing, *e.g.*, symptoms, diagnoses, and medical procedures to consistent, universally accepted, and easily ascertainable medical terminology.[7] Without medical coding, researchers would have to develop their own analytic approaches to group together similar events that have been described using highly variable language. Additionally, converting V-safe participants' Free-Text Responses to MedDRA codes ensures that CDC can disclose the codes to researchers and the public without the risk of inadvertently releasing a participant's highly sensitive health information.

32. CDC is conducting MedDRA coding of V-safe data to further the agency's understanding of vaccine adverse events, as well as to assist researchers to do the same. Therefore,

[6] CDC has converted data collected by the Vaccine Adverse Events Reporting System (VAERS) into MedDRA codes and released that information for research purposes for over 16 years.

[7] For example, reports of "a temperature of 102," "my temperature was high," and "his forehead was burning up," would all be converted to the MedDRA code "fever."

the MedDRA-coded data activity has the dual benefit of removing PII and providing standardized descriptions of symptoms and health events.

33. On July 26, 2023, the first set of MedDRA codes became available to the public at https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19-MedDRA-coded-text-responses/5biu-jjj3, which included 4.9 million converted Free-Text Response fields. On October 12, 2023, the datasets were updated to include an additional 240,000 converted Free-Text Response fields.

34. As this contract is already ongoing, and more than half of the Free-Text Response fields have already been translated into MedDRA codes, it cannot be "repurposed" at this stage to redact PII from the Free-Text Responses as Plaintiff suggests.

D. Alternative Methods for Processing Free-Text Responses Are Impracticable

35. Plaintiff argues that CDC should simply pay to have these Free-Text Responses processed. Although CDC has a discretionary budget, Plaintiff fails to understand the allocation process of how funds are distributed across Centers, Institutes, and Offices (CIOs). In order to even be considered for approval, a request such as this would first need to go through a planning process with no guarantee that it would be approved or that there would be funds available. This submission process would take at least a year to complete before an answer could be provided concerning funding. In addition, since the FOIA Office does not have the resources to process this request, if funding was approved, CDC would then need to initiate a solicitation for bids to contract for this service. At that point, taking into account the amount of time to procure a contract (typically up to a year-long process), and the time it would take to hire and properly train the contract staff, I estimate it would take close to 2 years before processing of these Free-Text Responses would begin.

36. Plaintiff's brief also asserts that CDC can easily provide the V-safe Free-Text Responses using the process established to remove PII from VAERS reports. However, this assertion ignores that separate contract mechanisms and funding would need to be established for such an activity.

37. The V-safe program was one of multiple systems employed by CDC and other federal agencies to develop a comprehensive understanding of the safety of COVID-19 vaccines. At CDC, other systems included the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment project (CISA). These programs were all operational systems prior to the COVID-19 pandemic, whereas the V-safe program was developed specifically to enhance VAERS reporting, to conduct rapid active surveillance for reactogenicity and health impact events reported directly by COVID-19 vaccine recipients, and to identify potential participants in CDC's COVID-19 vaccine pregnancy registry. VAERS and VSD are designed to detect and characterize rare and unexpected conditions whereas the V-safe program is designed to evaluate common reactogenicity events, to characterize the basic safety profile of COVID-19 vaccines with respect to common reactogenicity events (*e.g.*, injection site soreness, fever, muscle aches, etc.), and to monitor health impact events. Free text fields were included in the V-safe surveys to provide V-safe participants with an opportunity to report other symptoms or health events not specified in checkboxes on daily surveys and new or worsening symptoms or health events on weekly surveys. If participants indicated on any survey that they had received medical care for symptoms reported, the V-safe Call Center called them to assist with reporting this medical event, if applicable, to VAERS. The VAERS reporting is specifically designed to solicit additional details relevant to the assessment of an adverse event, including prescription history, chronic conditions, treatment received, and result or outcome of the adverse

event. The information made publicly available in VAERS is the type of vaccine received, date of vaccination, date of adverse event, current illnesses and medications, medical history, and demographic information. VAERS data is processed and made publicly available via a completely separate contract from the contract supporting MedDRA coding of data collected through the V-safe application.

38. Plaintiff also challenges the way the V-safe survey questions were drafted and suggests that the CDC FOIA Office utilize a PII detection service to process these Free-Text Responses. Although the Free-Text Response fields were not specifically drafted to capture PII, V-safe participants nonetheless included such PII in these fields while answering the questions. As explained in detail above, a review of these fields revealed that PII was included in the responses. However, the CDC FOIA Office does not have PII detection services to search for PII. These detection services were created to look for very specific information, which would not be applicable to all types of PII, especially in a narrative format. The PII detection programs require that the user know exactly what type of PII to search for, and without review of these fields it would be impossible to know all the types of PII that a V-safe participant may have included in a free-text response field. These PII detection services also do not take into account the fact that personal information that is not PII on its own may, when coupled with other personal information in the same narrative, lead to the identity of a person, or that human error may occur when typing information into the response field, making it more difficult to identify as PII. Therefore, even if use of such a detection program was possible, each Free-Text Response field would still require two levels of manual review by a human person to ensure all PII is redacted. The initial FOIA analyst would still have to manually review each Free-Text Response, as would the Team Lead to

make the final approval of any redactions, in accordance with FOIA Office procedures. As such, the anticipated processing time discussed above would remain unchanged.

V. CDC PROPERLY DENIED THE FEE WAIVER

39. I determined that Plaintiff's request for a waiver of all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) should be denied because Plaintiff failed to demonstrate in the January 3, 2023 FOIA request that the Freedom Coalition of Doctors for Choice disseminates information to the public. Further, Plaintiff failed to provide any evidence to warrant a grant of a fee waiver, but instead made general statements that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government."

40. Although the request for fee waiver did state that V-safe data would provide information on vaccine reactions and shed light on vaccine efficacy, it failed to take into account that information and data related to vaccine reactions was already disseminated to the public by CDC, and produced to Plaintiff in response to its FOIA request. The initial V-safe protocol was prepared in November 2020, and at the time, the V-safe application was configured to record no more than two doses of vaccine per participant. CDC staff also anticipated data collection for a relatively short period of time while other systems such as VAERS and VSD were accumulating informative data. Therefore, it was logical at the start of the program to estimate that public data would be available as described in versions 1 through 5 of the V-safe Protocol. However, the vaccination program in the United States evolved to include recommendations for booster doses of COVID-19 vaccine, and the V-safe application was updated to collect data on additional doses of vaccine beyond original expectations. In practice, this meant that the V-safe application

collected considerably more data and was operational for a longer period than initially anticipated due to the course of the pandemic and evolving COVID-19 vaccine recommendations.

41. In addition, I considered Plaintiff's fee category to be that of "Other requestor," therefore entitling Plaintiff to 2 hours of free search time, up to 100 pages of duplication without charge, and Plaintiff would not be charged for review time of those pages.[8] In this case, no fees were assessed because CDC's search took less than 2 hours, the information released to Plaintiff had already been reviewed and made public, and I determined to withhold the Free-Text Responses pursuant to FOIA Exemption 6.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on this 22 day of November 2023.

Roger Andoh

Roger Andoh
Freedom of Information Act Officer
Centers for Disease Control and Prevention Agency
for Toxic Substances and Disease Registry
U.S. Department of Health and Human Services

[8] See HHS FOIA Regulations at 45 CFR Part 5, Subpart E

EXHIBIT A

Submit New Request

23-00462-FOIA

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
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Ste. 104
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chris@cwiestlaw.com

Requester Default Category: All Others

General Information

Action Office	HQ CDC/ATSDR FOIA Office
Action Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
Request Type	FOIA
Requester Category	Non-Commercial Scientific
Delivery Mode	E-mail

Shipping Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills
State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Request Information

Description	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
Date Range for Record Search:From	10/01/2020
Date Range for Record Search:To	12/31/2022
Description Document	CDC v-safe free text request.pdf

Fee Information

Willing Amount	$25
Fee Waiver Requested	Yes ,CDC v-safe free text request.pdf
Fee Waiver Request Reason	See attached.
Willing to Pay All Fees	No

Billing Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills

State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Other Information

Name	
Company	
Phone	
Fax	
Email Address	
Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills
State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Expedite Information

Expedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

---

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 4, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated January 3, 2023. Your request assigned number is 23-00462-FOIA, and it has been placed in our complex processing queue (copy enclosed).

Extension of Time
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

☐ We reasonably expect to receive and review voluminous records in response to your request.
☐ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Irma S. Diaz at 770-488-6310 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing
You requested that we expedite processing your request. Your request is denied because:
☐ You have failed to show that there is an imminent threat to the life or physical safety of an individual.
☐ You have not demonstrated that you are a person primarily engaged in disseminating information.

Fees and Fee Waivers

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☐ You have failed to demonstrate that you disseminate information to the public.

☐ You have failed to provide enough information to warrant a waiver of fees.

Fee Category

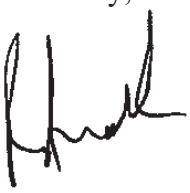
Because you are considered an "Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Appeal Rights

You have the right to appeal the agency's expedited processing and fee waiver response to your request. You may file your appeal with the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 5, 2023

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6310 or via email at jyo0@cdc.gov.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

23-00462-FOIA

EXHIBIT C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 12, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd. Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 3, 2023. Your request assigned number is 23-00462-FOIA, seeking:

> *"All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).* Date range: 10/01/2020-12/31/2022."

Please click on the following link to download a copy of the public v-safe data released by CDC. The data contains the registrant codes for all participants: *https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d*

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).

- The agency lacks the resources to manually review the data collected from these registrants.

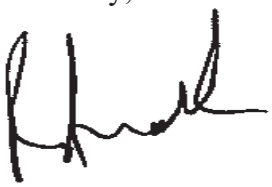
Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

Please click on the following link or copy into a web browser to download a copy of your records (download access is open for 90 days).
https://centersfordiseasecontrol.sharefile.com/d-s43a2254979c94ab6b5c52584509a351f

Appeal Rights

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 13, 2023.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#23-00462-FOIA

EXHIBIT D

Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

January 13, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request* #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter "Organization"). On January 3, 2023, I submitted on behalf of the Organization a request for records (hereafter "FOIA Request") from the files of the Centers for Disease Control and Prevention (hereafter "CDC") pursuant to the Freedom of Information Act (hereafter "FOIA"). On January 12, 2023, CDC responded to the FOIA Request (hereafter "Final Response"). The Organization writes now to appeal the Final Response.

Background:

On January 3, 2023, the Organization submitted a request to CDC for the following documents:

> *All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*

(Attachment 1.)

On January 12, 2023, CDC issued a Final Response letter which stated in relevant part:

> *Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:*
>
> - *There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).*
>
> - *The agency lacks the resources to manually review the data collected from these registrants.*

> *Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.*

(Attachment 2.)

Argument:

CDC's withholding of the requested free text fields (hereafter "requested records") violates FOIA in two ways. First, CDC has failed to provide any exemption to justify withholding the requested records and a proper final 'determination.' Secondly, even if it has determined that portions of the requested records are not reasonably segregable, and they contain information relevant to protected privacy interests under Exemption 6, CDC has failed to demonstrate whether such privacy interests outweigh the public's interest in disclosure.

1. **CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records.**

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide the Organization with an adequate 'determination' as required under FOIA. When the sufficiency of "the release of information under the FOIA" is challenged, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). "[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C.§ 552(a)(6)(A)(i) ("notify the person making such request of such determination *and reasons therefor*."). "The statutory requirement that the agency provide 'the reasons' for its 'determination' strongly suggests that the reasons are particularized to the 'determination' — most obviously, the specific exemptions that may apply to certain withheld records." *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep't of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency "satisfied its obligation to 'determine and communicate . . . the reasons for withholding any documents" because they "provided reasons by listing and defining the exemptions that the agency applied to the records" withheld.) Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency's obligations under FOIA. *Khine*, 943 F.3d at 967-968.

In this instance, CDC's Final Response did not provide the information necessary to justify its reasoning for withholding records. CDC's Final Response declares "the agency is withholding the v-safe free-text-fields data" but never details the applicable FOIA Exemption that justify its withholding. (*See* Attachment 2). CDC claims all "7.8 million free-text field entries collected from registered users . . . contain personal identifiable information (PII)." *Id*. CDC further claims

that it "lacks the resources to manually review the data collected from these registrants." First, if CDC does not have the resources to manually review the free text fields, how does it know all 7.8 million free text entries contain PII. It does not adequately prove this assertion. Second, CDC has not provided any information on whether most – if not all – the PII can be removed through more automated mechanisms, as opposed to only "manual[] review." For example, Social Security numbers, birthdates, phone numbers, registrant numbers, city names, etc. can likely be redacted through automated mechanism, or at least this information could be flagged for relatively easy manual redactions. Furthermore, if the free text fields are represented in a standardized template, and the PII is routinely detailed in certain boxes or locations in the template, the agency can automate a redaction overlay, that redacts these PII locations on every record. Therefore, CDC has not provided sufficient reasoning to withhold the requested records. For all the reasons described above, CDC has failed to justify withholding the requested records and provide the Organization with a sufficient final 'determination.' *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d 188-89.

2. **CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public's interest under Exemption 6.**

Even if CDC could demonstrate that the unreasonably segregable portions of the requested records contain protected privacy interests, CDC has failed to demonstrate those interests outweigh the public's interests in the requested records. "An agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi AG Media LLC v. U.S. Dep't of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a de minimis, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must "weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy." *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep't of State v. Washington Post Co*., 456 U.S. 595, 598 (1982).

In this instance, CDC's Final Response makes no indication whether the release of the information it has proven cannot be reasonably segregated would cause a "clearly unwarranted invasion of privacy." *Lepelletier*, 164 F.3d 46. FOIA does not flatly prohibit the release of personal information that could cause an invasion of privacy. It only protects the release of personal information that would cause a clearly unwarranted invasion of privacy. Thus, the determination on whether an invasion of privacy is clearly warranted or not depends on the

public's interest and benefit in obtaining the released material. *Id*. In this case, the requested information the Organization seeks has insurmountable importance to the public, and yet CDC's Final Response provides no indication whether the public's interest in the requested records was even considered.

In consideration of this appeal, as CDC goes back to balance the privacy interests in non-disclosure versus the public's interest in disclosure, Organization provides the following information to emphasize the insurmountable public interest in the requested records:

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which CDC currently possesses but is refusing to disclose, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

Failure to disclose this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. This would compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.[4] That is, for example, the core mission of React-19, a non-profit comprised of many individuals, and medical professionals, seriously injured from COVID-19 vaccines.

The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harms – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated. The information derived from the free text fields can help provide information to alleviate some of these issues.

The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign in order to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] The refusal to disclose the requested records would deny families the information they need to provide their informed consent to the external pressures and

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id*.

messaging resulting from the current administration's actions.

Lastly, if the requested information is disclosed, the Organization will, and has the capacity to make the information immediately available to the public. The Organization is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

Appellate Request:

For all the reasons detailed above, the Freedom Coalition of Doctors for Choice appeals CDC's Final Response and requests the agency make a determination with respect to this appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.
Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
Attorney
Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd
Ste. 104
Crestview Hills, KY 41017
Phone 5132571895
chris@cwiestlaw.com

Requester Default Category: All Others

General Information

Action Office	HQ CDC/ATSDR FOIA Office
Action Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
Request Type	FOIA
Requester Category	Non-Commercial Scientific
Delivery Mode	E-mail

Shipping Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills
State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Request Information

Description	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
Date Range for Record Search:From	10/01/2020
Date Range for Record Search:To	12/31/2022
Description Document	CDC v-safe free text request.pdf

Fee Information

Willing Amount	$25
Fee Waiver Requested	Yes ,CDC v-safe free text request.pdf
Fee Waiver Request Reason	See attached.
Willing to Pay All Fees	No

Billing Address

Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills

State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Other Information

Name	
Company	
Phone	
Fax	
Email Address	
Street1	25 Town Center Blvd
Street2	Ste. 104
City	Crestview Hills
State	Kentucky
State (Other)	
Country	United States
Zip Code	41017

Expedite Information

Expedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

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[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 12, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd. Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 3, 2023. Your request assigned number is 23-00462-FOIA, seeking:

> *"All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).* Date range: 10/01/2020-12/31/2022."

Please click on the following link to download a copy of the public v-safe data released by CDC. The data contains the registrant codes for all participants: *https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d*

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).

- The agency lacks the resources to manually review the data collected from these registrants.

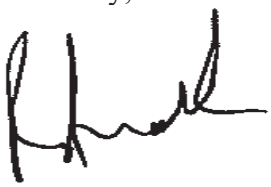
Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

Please click on the following link or copy into a web browser to download a copy of your records (download access is open for 90 days).
https://centersfordiseasecontrol.sharefile.com/d-s43a2254979c94ab6b5c52584509a351f

Appeal Rights

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 13, 2023.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#23-00462-FOIA

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00067-A-PHS

January 17, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on January 17, 2023. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

EXHIBIT F

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00067-A-PHS

July 3, 2023

Chris Wiest, Esq.
25 Town Center Boulevard, Suite 104
Crestview Hills, Kentucky 41017
Sent via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This responds to your Freedom of Information Act (FOIA) administrative appeal dated January 13, 2023, which was received by the Office of the Secretary's Freedom of Information Act Office (OS FOIA) and assigned tracking number 2023-00067-A-PHS. On January 3, 2023, you submitted a FOIA request to the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) on behalf of the Freedom Coalition of Doctors for Choice. Your request sought:

> All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).

CDC/ATSDR assigned the request tracking number 23-00462-FOIA. The agency sent a final response to your request on January 12, 2023, after which you appealed, asserting that "CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records" and that "CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public's interest under Exemption 6."

On June 16, 2023, you filed a federal lawsuit in the United States District Court for the Northern District of Texas, alleging *inter alia* that the Defendants (Centers for Disease Control and Prevention and U. S. Department of Health and Human Services) have not timely responded to this administrative appeal.

CONCLUSION:

Title 45 of the Code of Federal Regulations, Section 5.63, states, "If a requester files a FOIA lawsuit in reference to an appeal, [HHS] will cease processing the appeal." Because you filed

suit on June 16, 2023, this office is obligated to stop processing your appeal. Therefore, appeal 2023-00067-A-PHS is hereby administratively closed.

Alesia Y. Williams
Director, FOIA Appeals and Litigation
FOI/Privacy Acts Division

Copy to:
CDC/ATSDR FOIA Office

EXHIBIT G

Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

March 31, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs U.S. Department of Health and Human Services Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: Fee Waiver Appeal of FOIA Request #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter "Freedom Coalition"). On January 3, 2023, on behalf of Freedom Coalition, I submitted a request for records (hereafter "FOIA Request") from the files of the Centers for Disease Control and Prevention (hereafter "CDC") pursuant to the Freedom of Information Act (hereafter "FOIA"). On January 4, 2023, CDC acknowledged the FOIA Request and denied Freedom Coalition's fee waiver request. Freedom Coalition writes now to appeal this denial.

Background:

On January 3, 2023, Freedom Coalition submitted a request to CDC for the following documents:

> *All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*

(Attachment 1.)

As part of its request, Freedom Coalition requested that CDC waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government. Freedom Coalition detailed three ways the disclosure of the requested information would contribute to that understanding. It stated:

> (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe

> participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization;(2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and
>
> (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the [Freedom Coalition] requests will not contribute to any commercial activities.

On January 4, 2023, CDC acknowledged the request, assigned it request number 23-00462-FOIA, and denied Freedom Coalition's request for a fee waiver stating in relevant part:

> You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:
>
> ☐ You have failed to demonstrate that you disseminate information to the public.
>
> ☐ You have failed to provide enough information to warrant a waiver of fees.

(Attachment 2.)

CDC issued a final response to the request on January 12, 2023, declaring "the agency is withholding the v-safe free-text-fields data." (Attachment 3.) Freedom Coalition submitted an appeal challenging the agency's withholding of responsive records, and the appeal was officially acknowledged on January 17, 2023. (Attachment 4.) Despite the passage of over 30 business days, CDC has failed to make any determination with respect to Freedom Coalition's appeal.

Argument:

CDC should waive any and all fees or charges associated with the processing of Freedom Coalition's FOIA Request because Freedom Coalition has sufficiently detailed how the requested information is in the public interest and likely to contribute significantly to the public understanding of the operations or activities of CDC. Additionally, even if it is determined Freedom Coalition is not entitled to a complete fee waiver, its status as an educational institution requester, or member of the media, entitles it to reduced fees and costs. Moreover, Freedom Coalition's entitled to reduced fees and costs because CDC failed to abide by the time limits of FOIA.

1. The requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government

Under FOIA, "[d]ocuments shall be furnished without any charge or [reduced] . . . if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. Furthermore, under FOIA, federal agencies are required to "promulgate regulations . . . specifying the schedule of fees applicable to the processing of requests . . . and establishing procedures and guidelines for determining when such fees should be waived or reduced." 5 U.S.C. § 552(a)(4)(A)(i). The U.S. Department of Health and Human Services ("HHS"), CDC's parent department, has promulgated regulations regarding fees and fee waivers applicable to FOIA Requests. 45 C.F.R. §§ 5.51 – 5.54.

HHS regulations provide that the agency "must furnish records responsive to a request without charge or at a reduced rate" if it determines that: (1) "[d]isclosure of the requested information would shed light on the operations or activities of the government"; (2) "[d]isclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities"; and (3) "[t]he disclosure must not be primarily in the commercial interest of the requester." 45 C.F.R. § 5.54(b). All three factors are present here.

a. Disclosure of the requested information would shed light on the operations or activities of the government

The disclosure of the information Freedom Coalition has requested – all data from v-safe's free-text fields – will shed light on the operations or activities of the government. As explained below, the relevant free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines. Therefore, the disclosure of the information will shed light on whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues that impacted its relevant policies or regulatory decisions and recommendations.

CDC claims that the current "COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in U.S. history[.]"[1] CDC also explained that its leading vaccine safety system, the Vaccine Adverse Events Reporting System ("VAERS"), was incapable of determining causation and was otherwise unreliable to assess the safety of COVID-19 vaccines. As a result, CDC deployed a new safety monitoring system for the COVID-19 vaccines: **v-safe**.

V-safe is CDC's premier safety system for tracking the safety of COVID-19 vaccines. V-safe is an online software program, accessible through the use of a smart phone, that allows vaccine recipients to "tell CDC about any side effects after getting the COVID-19 vaccine."[2] The purpose of the program, as explained by CDC, "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important

[1] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

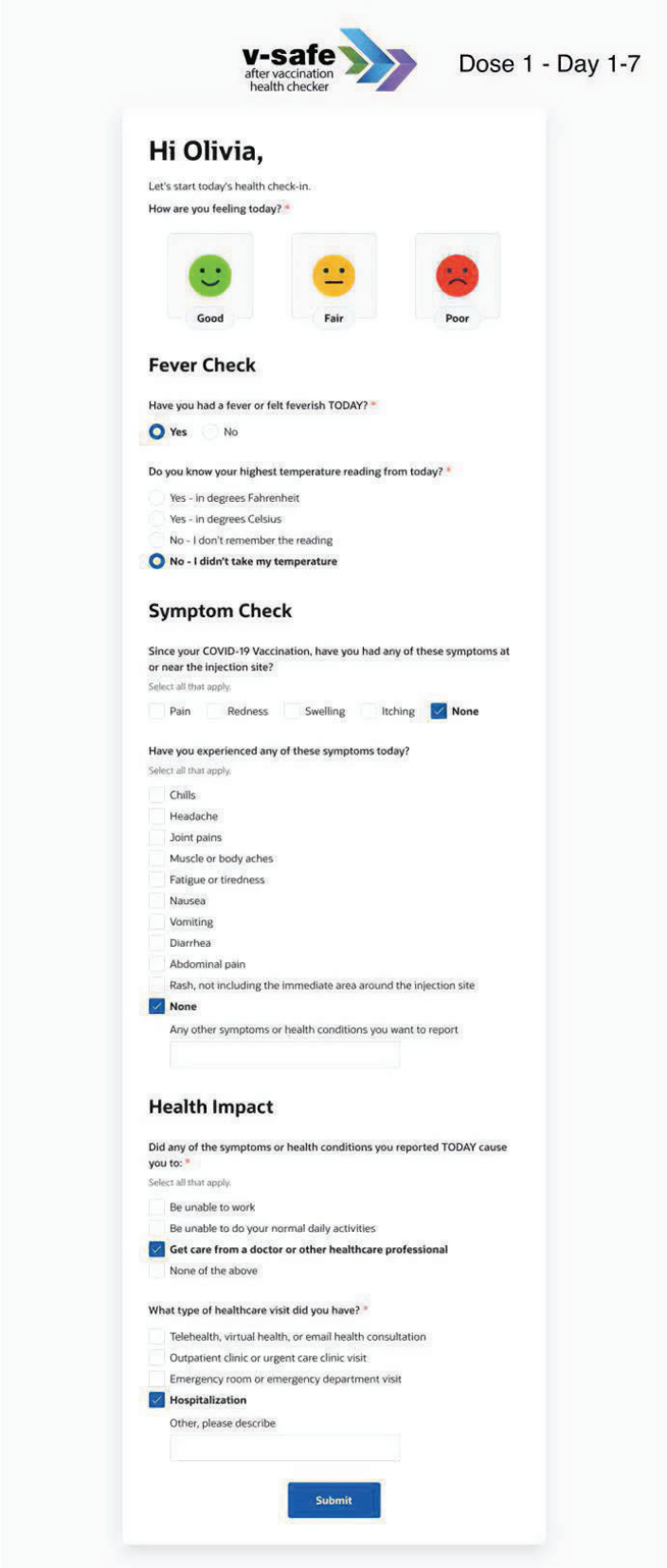
[2] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

adverse events and safety issues that might impact policy or regulatory decisions."[3]

V-safe collected COVID-19 vaccine safety information in two ways from its approximate 10 million users. The first is with check-the-box questions. The second is with free-text fields.

With regard to the check-the-box data collected, it is limited to two categories of information. The first asks v-safe users to select one or more of 10 symptoms that occurred within the first week after vaccination. For example, see the image below:

[3] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.


v-safe
after vaccination health checker
Dose 1 - Day 1-7
Hi Olivia,
Let's start today's health check-in.
How are you feeling today? *
Good
Fair
Poor
Fever Check
Have you had a fever or felt feverish TODAY? *
Yes
No
Do you know your highest temperature reading from today? *
Yes - in degrees Fahrenheit
Yes - in degrees Celsius
No - I don't remember the reading
No - I didn't take my temperature
Symptom Check
Since your COVID-19 Vaccination, have you had any of these symptoms at or near the injection site?
Select all that apply.
Pain
Redness
Swelling
Itching
None
Have you experienced any of these symptoms today?
Select all that apply.
Chills
Headache
Joint pains
Muscle or body aches
Fatigue or tiredness
Nausea
Vomiting
Diarrhea
Abdominal pain
Rash, not including the immediate area around the injection site
None
Any other symptoms or health conditions you want to report
Health Impact
Did any of the symptoms or health conditions you reported TODAY cause you to: *
Select all that apply.
Be unable to work
Be unable to do your normal daily activities
Get care from a doctor or other healthcare professional
None of the above
What type of healthcare visit did you have? *
Telehealth, virtual health, or email health consultation
Outpatient clinic or urgent care clinic visit
Emergency room or emergency department visit
Hospitalization
Other, please describe
Submit

This list of symptoms are the same symptoms CDC says are normal to occur after vaccination and are actually a sign the vaccine is working by producing an immune response.[4] Therefore, for the assessment of the overall safety of COVID-19 vaccines, it was pointless to gather this information regarding these 10 symptoms.

The only other check-the-box safety information collected (other than symptoms) is asking v-safe users whether they needed medical care, missed school or work, or could not perform normal daily activities (the "**health impact data**"). If the user selected needing medical care, they were then asked to select whether they sought telehealth, urgent care, emergency care, or were hospitalized. The health impact data, unlike the check-the-box symptoms data, is collected beyond the first week after injection, and is collected weekly for the first six weeks after injection, then again at 3, 6 and 12 months.

While the collection of the health impact data is an important part of gaging the safety of the COVID-19 vaccines, the free-text fields provide the only opportunity for v-safe users to report more complex and serious adverse events that occurred after vaccination. For example, in the first version of the v-safe protocol, prior to its launch, CDC identified the following adverse events of special interest in a chart titled Prespecified Medical Conditions:

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

(Attachment 5.)

CDC also identified many of these adverse events as potential harms of concern from COVID-19

[4] See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.

vaccines, in a presentation on October 30, 2020, titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[5] Despite CDC itself directly identifying these adverse events as harms of potential concern, it did not include check-the-box options for users to report these harms, nor did it even provide any check-the-box options for common symptoms from these harms. Instead, CDC oddly purposely chose to limit reporting of any such adverse events to the free-text fields, a data collection method that is far more difficult to standardize and tabulate.

CDC had an obligation to properly review and tabulate the data to detect and evaluate clinically important adverse events and safety issues.[6] Until this critical data obtained from these free-text fields is released to the public, there is no way for the public and scientific and medical community to determine whether CDC adequately acted upon *the most critical information it obtained from v-safe users.* In addition, the disclosure of this critical information will shed light on the legitimacy and reasonableness of the policy and regulatory decisions and recommendations CDC made with respect to the COVID-19 vaccines.

Therefore, the release of the requested information is in the public interest because it is likely to contribute significantly to the public's understanding of the operations or activities of the government. Thus, the first factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

b. Disclosure of the requested information would likely to contribute significantly to public understanding of governmental operations or activities

The disclosure of the data obtained from the free-text fields would significantly contribute to the public's understanding of whether CDC properly analyzed the information to detect and evaluate clinically important adverse events and safety issues, and whether it implemented the correct policy or regulatory decisions based off the data it received. Currently, CDC claims it received 7.8 million free-text entries from v-safe users. (Attachment 3.) However, CDC has not allowed the public to assess the critically important data obtained from these free-text fields.

As explained in the section above, because of how CDC structured the v-safe program, these free-text entries provide the only opportunity to report serious adverse events in the v-safe system. Moreover, these free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines because they were collected from a known sample size of participants directly reporting their symptoms and reactions. Thus, the rate at which an adverse event is reported can be calculated and relied upon. Therefore, the disclosure of the requested information would likely contribute significantly to public understanding behind the legitimacy of CDC's numerous policy and regulatory decisions and recommendations based on its assertion that the COVID-19 vaccines are safe and serious adverse events are *statistically rare*.[7]

The numerous policy and regulatory decisions and recommendations CDC made regarding the COVID-19 vaccines played a major role in influencing large segments of society to mandate

[5] https://stacks.cdc.gov/view/cdc/97350 at 17.

[6] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[7] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

the receipt of the COVID-19 vaccines. Largely because of these vaccine mandates, more than 265 million Americans received at least one COVID-19 vaccine.[8] Therefore, a large segment of the public would likely be interested in learning the rates of serious adverse events that were reported in v-safe, CDC's premier safety system for tracking the safety of COVID-19 vaccine.

Freedom Coalition is in a unique position to facilitate the review, analysis, and dissemination of the information it receives from this request. Freedom Coalition is a nonprofit organization that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database. The coalition is made up of medical and public health professionals, scientists, and journalists. It takes no position on this data other than that it should be made available to the public and scientific community as soon as possible. All data obtained will be made available on its website, www.drsforchoice.org, upon receipt. Its network of uniquely qualified members and supporters will enable the information obtained from this request to be easily and meaningfully distributed to wide segment of the American public.

Therefore, the disclosure of the requested information would likely contribute significantly to public understanding of CDC's operations and activities. Thus, the second factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

c. The disclosure is not primarily in the commercial interest of the requester

The information Freedom Coalition seeks is not "primarily in the commercial interest of the requester." The disclosure of records from this request will not contribute to any commercial activities. Freedom Coalition is a non-profit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database. (Attachment 6.) It fully intends to disseminate the disclosed information for free and will not profit from the disclosure of the requested information. Thus, the third factor weighs heavily in favor of granting Freedom Coalition a fee waiver.

Freedom Coalition has established all the criteria HHS and CDC find necessary to furnish records without charge, therefore the fee waiver request should be granted. 45 C.F.R. § 5.54(b).

2. Freedom Coalition is not an "Other Requester"

Even if CDC determines a full fee waiver is not appropriate, Freedom Coalition should be considered an educational institution requester, or a member of the media. As explained above, Freedom Coalition is a nonprofit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database.[9] It intends to provide access to the disclosed data to the public for free through its website, and its network of members and supporters which includes medical personnel and journalists. Therefore, at the very least, Freedom Coalition is "entitled to search time, review time, and up to 100 pages of duplication (or the cost equivalent for other media) without charge." 45 U.S.C. § 5.53(b).

[8] https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.

[9] https://drsforchoice.org/.

3. CDC is required to waive fees when it fails to abide by the time limits of FOIA.

CDC should waive or reduce fees because it failed to make a determination with respect to Freedom Coalition's appeal within the time limits prescribed by FOIA. An agency must make a determination with respect to a requester's appeal within 20 business days of its receipt. 5 U.S.C. § 522(a)(6)(A)(ii). If the agency provides an adequate notice of "unusual circumstances" the deadline for the agency's determination can be extended to a total of 30 business days. 5 U.S.C. § 522(a)(6)(B)(i). When an agency fails to comply with these deadlines "and agency shall not assess any search fees [or duplications fees]." 5 U.S.C. §522 (a)(4)(A)(viii)(I). Even when unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, an agency may not charge search or duplications fees unless the agency has discussed with the requester how it could effectively limit the scope of the request. 5 U.S.C. § 522(a)(4)(A)(viii)(II).

In this instance, CDC failed to make a determination with respect to Freedom Coalition's appeal within 30 days. Furthermore, CDC never discussed with Freedom Coalition how it could effectively limit the scope of the request. Therefore, Freedom Coalition should not have to pay all the fees CDC incurs or incurred during the processing of its request. 5 U.S.C. § 522(a)(4)(A)(viii)(I); 5 U.S.C. § 522(a)(4)(A)(viii)(II).

Appellate Request

For all the reasons detailed above, Freedom Coalition appeals CDC's fee waiver denial and requests the agency make a determination with respect to this fee waiver appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Regards,

/s Christopher Wiest

Christopher Wiest

Attachment 1

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

o modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
ttorney
hris Wiest, Attorney at Law, PLLC
5 Town Center Blvd
te. 104
restview Hills, KY 41017
hone 5132571895
hris@cwiestlaw.com

equester Default Category: All Others

eneral Information

ction Office	HQ CDC/ATSDR FOIA Office
ction Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
equest Type	FOIA
equester Category	Non-Commercial Scientific
elivery Mode	E-mail

hipping Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

equest Information

escription	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
ate Range for Record earch:From	10/01/2020
ate Range for Record earch:To	12/31/2022
escription Document	CDC v-safe free text request.pdf

ee Information

illing Amount	$25
ee Waiver Requested	Yes ,CDC v-safe free text request.pdf
ee Waiver Request Reason	See attached.
illing to Pay All Fees	No

illing Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills

tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

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treet2	Ste. 104
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tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

xpedite Information

xpedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

---

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 4, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated January 3, 2023. Your request assigned number is 23-00462-FOIA, and it has been placed in our complex processing queue (copy enclosed).

Extension of Time
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

☐ We reasonably expect to receive and review voluminous records in response to your request.
☐ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Irma S. Diaz at 770-488-6310 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing
You requested that we expedite processing your request. Your request is denied because:
☐ You have failed to show that there is an imminent threat to the life or physical safety of an individual.
☐ You have not demonstrated that you are a person primarily engaged in disseminating information.

Fees and Fee Waivers

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☐ You have failed to demonstrate that you disseminate information to the public.

☐ You have failed to provide enough information to warrant a waiver of fees.

Fee Category

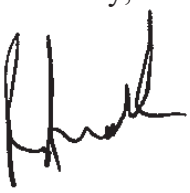
Because you are considered an "Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Appeal Rights

You have the right to appeal the agency's expedited processing and fee waiver response to your request. You may file your appeal with the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 5, 2023

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6310 or via email at jyo0@cdc.gov.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

23-00462-FOIA

Attachment 3

Chris Wiest, Attorney at Law, PLLC
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
(513)257-1895 (cellular)
chris@cwiestlaw.com
*admitted in Kentucky and Ohio

January 13, 2023

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request* #23-00462-FOIA

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter "Organization"). On January 3, 2023, I submitted on behalf of the Organization a request for records (hereafter "FOIA Request") from the files of the Centers for Disease Control and Prevention (hereafter "CDC") pursuant to the Freedom of Information Act (hereafter "FOIA"). On January 12, 2023, CDC responded to the FOIA Request (hereafter "Final Response"). The Organization writes now to appeal the Final Response.

Background:

On January 3, 2023, the Organization submitted a request to CDC for the following documents:

> *All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).*

(Attachment 1.)

On January 12, 2023, CDC issued a Final Response letter which stated in relevant part:

> *Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:*
>
> - *There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).*
>
> - *The agency lacks the resources to manually review the data collected from these registrants.*

> *Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.*

(Attachment 2.)

Argument:

CDC's withholding of the requested free text fields (hereafter "requested records") violates FOIA in two ways. First, CDC has failed to provide any exemption to justify withholding the requested records and a proper final 'determination.' Secondly, even if it has determined that portions of the requested records are not reasonably segregable, and they contain information relevant to protected privacy interests under Exemption 6, CDC has failed to demonstrate whether such privacy interests outweigh the public's interest in disclosure.

1. **CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records.**

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide the Organization with an adequate 'determination' as required under FOIA. When the sufficiency of "the release of information under the FOIA" is challenged, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). "[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C.§ 552(a)(6)(A)(i) ("notify the person making such request of such determination *and reasons therefor*."). "The statutory requirement that the agency provide 'the reasons' for its 'determination' strongly suggests that the reasons are particularized to the 'determination' — most obviously, the specific exemptions that may apply to certain withheld records." *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep't of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency "satisfied its obligation to 'determine and communicate . . . the reasons for withholding any documents" because they "provided reasons by listing and defining the exemptions that the agency applied to the records" withheld.) Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency's obligations under FOIA. *Khine*, 943 F.3d at 967-968.

In this instance, CDC's Final Response did not provide the information necessary to justify its reasoning for withholding records. CDC's Final Response declares "the agency is withholding the v-safe free-text-fields data" but never details the applicable FOIA Exemption that justify its withholding. (*See* Attachment 2). CDC claims all "7.8 million free-text field entries collected from registered users . . . contain personal identifiable information (PII)." *Id*. CDC further claims

that it "lacks the resources to manually review the data collected from these registrants." First, if CDC does not have the resources to manually review the free text fields, how does it know all 7.8 million free text entries contain PII. It does not adequately prove this assertion. Second, CDC has not provided any information on whether most – if not all – the PII can be removed through more automated mechanisms, as opposed to only "manual[] review." For example, Social Security numbers, birthdates, phone numbers, registrant numbers, city names, etc. can likely be redacted through automated mechanism, or at least this information could be flagged for relatively easy manual redactions. Furthermore, if the free text fields are represented in a standardized template, and the PII is routinely detailed in certain boxes or locations in the template, the agency can automate a redaction overlay, that redacts these PII locations on every record. Therefore, CDC has not provided sufficient reasoning to withhold the requested records. For all the reasons described above, CDC has failed to justify withholding the requested records and provide the Organization with a sufficient final 'determination.' *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d 188-89.

2. **CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public's interest under Exemption 6.**

Even if CDC could demonstrate that the unreasonably segregable portions of the requested records contain protected privacy interests, CDC has failed to demonstrate those interests outweigh the public's interests in the requested records. "An agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi AG Media LLC v. U.S. Dep't of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a de minimis, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must "weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy." *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep't of State v. Washington Post Co*., 456 U.S. 595, 598 (1982).

In this instance, CDC's Final Response makes no indication whether the release of the information it has proven cannot be reasonably segregated would cause a "clearly unwarranted invasion of privacy." *Lepelletier*, 164 F.3d 46. FOIA does not flatly prohibit the release of personal information that could cause an invasion of privacy. It only protects the release of personal information that would cause a clearly unwarranted invasion of privacy. Thus, the determination on whether an invasion of privacy is clearly warranted or not depends on the

public's interest and benefit in obtaining the released material. *Id*. In this case, the requested information the Organization seeks has insurmountable importance to the public, and yet CDC's Final Response provides no indication whether the public's interest in the requested records was even considered.

In consideration of this appeal, as CDC goes back to balance the privacy interests in non-disclosure versus the public's interest in disclosure, Organization provides the following information to emphasize the insurmountable public interest in the requested records:

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which CDC currently possesses but is refusing to disclose, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

Failure to disclose this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. This would compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.[4] That is, for example, the core mission of React-19, a non-profit comprised of many individuals, and medical professionals, seriously injured from COVID-19 vaccines.

The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harms – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated. The information derived from the free text fields can help provide information to alleviate some of these issues.

The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign in order to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] The refusal to disclose the requested records would deny families the information they need to provide their informed consent to the external pressures and

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id*.

messaging resulting from the current administration's actions.

Lastly, if the requested information is disclosed, the Organization will, and has the capacity to make the information immediately available to the public. The Organization is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

Appellate Request:

For all the reasons detailed above, the Freedom Coalition of Doctors for Choice appeals CDC's Final Response and requests the agency make a determination with respect to this appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.
Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 1

Submit New Request

23-00462-FOIA

Requester Details

o modify request details please update your requester profile or contact the our office for assistance.

Christopher Wiest
ttorney
hris Wiest, Attorney at Law, PLLC
5 Town Center Blvd
te. 104
restview Hills, KY 41017
hone 5132571895
hris@cwiestlaw.com

equester Default Category: All Others

eneral Information

ction Office	HQ CDC/ATSDR FOIA Office
ction Office Instructions	1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
equest Type	FOIA
equester Category	Non-Commercial Scientific
elivery Mode	E-mail

hipping Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

equest Information

escription	All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).
ate Range for Record earch:From	10/01/2020
ate Range for Record earch:To	12/31/2022
escription Document	CDC v-safe free text request.pdf

ee Information

illing Amount	$25
ee Waiver Requested	Yes ,CDC v-safe free text request.pdf
ee Waiver Request Reason	See attached.
illing to Pay All Fees	No

illing Address

treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills

tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

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treet1	25 Town Center Blvd
treet2	Ste. 104
ity	Crestview Hills
tate	Kentucky
tate (Other)	
ountry	United States
ip Code	41017

xpedite Information

xpedite Reason	See attached.

January 3, 2023

Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

RE: Expedited Processing Requested for Accompanying Freedom of Information Act (FOIA) Request for V-Safe's Free Text Fields

Dear FOIA Officer,

I am writing on behalf of the non-profit organization Freedom Coalition of Doctors for Choice ("**Organization**") and its members. Pursuant to the Freedom of Information Act ("**FOIA**"), the members of this organization would like CDC to provide the following records in an expedited manner and in electronic form: **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

Freedom Coalition of Doctors for Choice is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the Organization requests will not contribute to any commercial activities.

Furthermore, the Organization also requests CDC provide expedited processing for this request. The information requested concerns matters of urgent public concern. The Organization's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

The requester is primarily engaged in disseminating information

The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free-text fields in the CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about Covid-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

There is an urgency to inform the public concerning actual or alleged Federal Government activity.

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns Federal Government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of the Organization's FOIA request.

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[1] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[2] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users/registrants, generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as the CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[3] Without this information, which the CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters. Preventing the public and the scientific community from immediately accessing,

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[2] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

analyzing, and synthesizing this information compromises the public's significant recognized interest of informed consent.[4]

The information sought is more urgent than ever because the federal government has recently implemented policies and messaging campaigns in order to promote the public's consent and access to the COVID-19 vaccines and boosters. However, to derive the public's informed consent, the federal government has an obligation to balance its messaging with – at the very least – access to the information it possesses regarding the possible risks and harms from receiving these medical products.

For example, transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[5] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school, based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

As another example, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[6] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[7] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Therefore, as demonstrated above, the Organization has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged Federal Government activities. Thus, the Organization's request for expedited processing should be granted.

---

[4] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any . . . ." 10 NYCRR § 405.7 (b)(9).

[5] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

[6] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[7] *Id.*

CDC's records are subject to disclosure under FOIA and are not otherwise exempt from disclosure pursuant to FOIA's nine statutory exemptions. To the extent that a determination is made by CDC that any limited portions of the records described above will be withheld from disclosure for this request, the Organization requests that the CDC segregate and disclose any portions of the records that are not exempt. Please expressly identify any exempt responsive records (or portions thereof) and the applicable FOIA exemptions for any responsive materials withheld for this FOIA request.

Our organization also requests that the agency provide an estimated date of completion for this request. Please inform me in writing if there are any "unusual circumstances" that will cause delay in responding to this FOIA request or providing the records which are requested.

If you have any questions regarding this FOIA request, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Thank you in advance for your assistance in processing this request.

Regards,

/s Christopher Wiest
Christopher Wiest

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 12, 2023

SENT VIA EMAIL

Christopher Wiest
Attorney at Law, PLLC
25 Town Center Blvd. Suite 104
Crestview Hills, Kentucky 41017
Via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of January 3, 2023. Your request assigned number is 23-00462-FOIA, seeking:

> *"All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).* Date range: 10/01/2020-12/31/2022."

Please click on the following link to download a copy of the public v-safe data released by CDC. The data contains the registrant codes for all participants: *https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d*

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).

- The agency lacks the resources to manually review the data collected from these registrants.

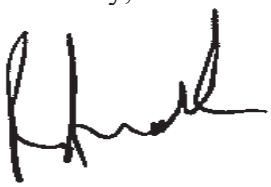
Alternatively, we are providing you with a copy of the "v-safe motivation survey" dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

Please click on the following link or copy into a web browser to download a copy of your records (download access is open for 90 days).
https://centersfordiseasecontrol.sharefile.com/d-s43a2254979c94ab6b5c52584509a351f

Appeal Rights

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 13, 2023.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#23-00462-FOIA

Attachment 4

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00067-A-PHS

January 17, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on January 17, 2023. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

Attachment 5

V-safe active surveillance for COVID-19 vaccine safety

Protocol summary

V-safe is an active surveillance program to monitor the safety of COVID-19 vaccines during the period when the vaccines are authorized for use under Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and possibly early after vaccine licensure. V-safe is a new smartphone-based system that uses text messaging to initiate web-based survey monitoring in the form of periodic health check-ins to assess for potential adverse events following vaccination. CDC will use the follow-up capability of the existing Vaccine Adverse Event Reporting System (VAERS) call center to conduct active telephone follow-up on recipients reporting a significant health impact during v-safe health check-ins. The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.

Background and significance

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Following the emergence of COVID-19 in China in late 2019, the first confirmed U.S. cases were detected in January 2020. With rapid human-to-human transmission occurring, the United States declared a public health emergency in February 2020, followed by a national emergency in March 2020 (1). As of November 18, 2020, there have been 11,300,635 cases of COVID-19 disease in the United States and 247,834 deaths (2). A key U.S. pandemic response initiative is Operation Warp Speed, a public-private partnership established in May 2020, with a goal to develop and deliver safe and effective COVID-19 vaccine(s) to the U.S. population by early 2021 (3).

Post-authorization/post-approval vaccine safety monitoring is a federal government responsibility, with the Centers for Disease Control and Prevention (CDC) and the FDA sharing most of the responsibility along with other federal agencies involved in healthcare delivery (e.g., Veterans Affairs, Department of Defense, Indian Health Service). Initial safety assessment

begins in early vaccine development and expands during phased clinical trials in humans. Clinical trials are effective at identifying and characterizing common adverse events, such as local and systemic reactions. However, even large clinical trials, like the COVID-19 vaccine clinical trials that are enrolling tens of thousands of volunteers, might not be large enough to detect rare adverse events (for example, those occurring at rates of <1 per 100,000 people vaccinated). Furthermore, for some clinical trials of COVID-19 vaccines, the follow-up period to monitor for possible adverse events with delayed onset may not be completed for all subjects prior to issuance of an EUA or licensure. Additionally, exclusion criteria for clinical trials may limit generalizability of safety and efficacy findings to special populations, such as those with certain chronic illnesses or pregnant women (4). For these reasons, robust post-authorization/approval safety monitoring of COVID-19 vaccines is a public health priority.

To meet the safety data needs for COVID-19 vaccine pharmacovigilance during the post-authorization/approval period, CDC will implement v-safe, a smartphone-based system that uses text messaging to initiate web-based surveys to monitor for adverse events following vaccination. The surveillance process triggers active telephone follow-up on vaccinated individuals reporting a significant health impact during v-safe health check-ins.

Goals and objectives

Goals

- Characterize the safety profile of COVID-19 vaccines.

- Rapidly monitor and identify potential safety problems associated with COVID-19 vaccines that would impact policy or regulatory decisions.

Objectives

- Characterize the local and systemic reactogenicity of COVID-19 vaccines during the first week post-vaccination (days 0-7).

- Identify and characterize clinically important adverse events following COVID-19 vaccination during a 6-week post-vaccination follow-up period.

- Monitor the long(er)-term (3, 6, and 12 months post-vaccination) safety of COVID-19 vaccines.

Methods

Surveillance population

All people in the United States who receive a COVID-19 vaccination will be eligible to enroll in v-safe for the duration of the v-safe program. Surveys will be available in English, Spanish, Simplified Chinese, Vietnamese, and Korean languages.

Enrollment criteria:

- Participants must have received a COVID-19 vaccination.
- Participants must possess a smartphone with a valid US telephone number. More than one individual may use the same smartphone/telephone number (i.e., shared smartphone).

Enrollment

The v-safe program will commence when COVID-19 vaccines are authorized or approved for use and become available to the U.S. population. Vaccination may occur at a mass vaccination clinic, an occupational health clinic, a public health clinic, a healthcare provider's office, a pharmacy, or other setting. At the time of vaccination, the healthcare provider will briefly describe the v-safe program using a prescribed script (Attachment 1). In addition, the healthcare provider will provide the vaccinated patient with an information sheet that includes a brief description of the program, a URL and a scannable QR code, and enrollment instructions.

Vaccinated individuals can enroll in v-safe immediately following vaccination. If they do not enroll immediately, they can decide to participate in v-safe at any time up to 42 days following the first vaccination. For vaccine recipients whose vaccination information is captured in CDC's Vaccine Administration Management System (VAMS), VAMS will send recipients a reminder text message about v-safe 24 hours after vaccination (5). Participation in v-safe is voluntary and

people can opt out at any time by texting "STOP" when v-safe sends a reminder text message; people can also start v-safe again by texting "UNSTOP."

Once a vaccinated individual decides to enroll in v-safe, the individual will either scan his/her mobile phone camera over the QR code on the information sheet or type in the v-safe URL to access the v-safe registration website.

Registration information includes:

- First name
- Last name
- Mobile phone number
- Date of birth
- Sex
- Zip code

The registration system will ask the participant to verify their phone number by sending a text message with a verification code. The participant will enter the texted code to verify their identity. After that, the participant will be asked to record information on their first COVID-19 vaccination, including the vaccine manufacturer and the vaccination date. If the v-safe participant does not know this information, they are encouraged to refer to the vaccination record card they received or to contact their healthcare provider.

Once a participant has registered and provided information on their COVID-19 vaccination, they will be prompted to take an initial v-safe health check-in survey. The survey will be dependent on the vaccination date and dose number (if applicable) entered during registration. Subsequently, text messages will be sent to their smartphone with a link to a web-based survey at 2:00 pm (local time based on zip code entered at registration) on the schedule listed below.

Electronic health check-in schedule

The schedule for electronic health check-ins is as follows:

1. Day 0 (day of vaccination)

2. Daily on days 1-7 (the 1st week post-vaccination)

3. Weekly starting day 14 (2nd week post-vaccination) to up to day 42 (6th week post-vaccination) if no 2nd dose of COVID-19 vaccine is received

    a. If participant receive a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through steps 1-3 above based on time since the 2nd dose.

4. At 3, 6, and 12 months post-vaccination following 2nd dose vaccination or following first dose if no 2nd dose is received

Daily surveys expire at midnight on the day of the survey and weekly surveys expire at midnight on the last day of the week before the next weekly survey period. The day 42 survey will expire on day 48 at midnight. Monthly surveys will be available for 6 full days following receipt of the survey, expiring at midnight. A participant can enroll in v-safe up to 42 days during the post-vaccination follow-up period after the first dose, but cannot go back and complete surveys that have expired (i.e., it will be prospective from the time of enrollment). In addition, a participant cannot revise their survey once it has been submitted. After submission, the participant is told that depending on his/her answers, someone from CDC might call to follow up.

Active telephone follow-up

If, during any v-safe health check-in, a participant reports a significant health impact event, defined as per the survey: a) missed work, and/or b) unable to do normal daily activities, and/or c) got care from a doctor or other healthcare professional, VAERS call center staff will be informed and active telephone follow-up will be initiated to check on the patient and take a VAERS report if appropriate. VAERS is an existing national spontaneous reporting system that is co-managed by FDA and CDC. It serves as an early warning system for adverse events following vaccination (6).

VAERS call center staff will be notified of participants who have reported a significant health impact event via a data set that will be created from the v-safe survey system. The data set will include the following variables:

- Unique v-safe id
- First name
- Last name
- Phone number
- Sex
- Zip code
- Flagged health impact question
- Flagged health impact response(s) survey number (dose/survey [i.e., Dose2D0])

Using this information, the VAERS call center staff will call participants identified in the data set and complete a VAERS report (located at https://vaers.hhs.gov) by phone if appropriate.

Data collection, quality, and management

V-safe data will be collected, managed, and housed on a secure server by Oracle. Through Health and Human Services (HHS), Oracle has donated IT services to any agency conducting COVID-19 related activities. Oracle is providing IT support for v-safe. All data will be stored, processed, and transmitted in accordance with the Federal Information Security Modernization Act (FISMA) and based on NIST standards. Data will be housed in *Oracle Cloud Infrastructure (OCI) U.S. Government Cloud tenancy*; the OCI U.S. government tenancy is Federal Risk and Authorization Management Program (FEDRAMP) approved (7).

Per Oracle's internal policies, Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the CDC IT contractor's secure server. The v-safe system employs strict security measures appropriate for the level of sensitivity of the data. Data received by CDC will be stored on an internal secure CDC/ISO server and access will be limited to authorized personnel.

Oracle will create a data set for the VAERS call center that includes those participants who reported having a heath impact event. CDC-badged contractors will access these data in order to provide call center representatives with information needed to follow up with participants (see "Active telephone follow-up" above). The VAERS call center staff is employed specifically for v-safe follow-up and is associated with the overall VAERS contractor.

VAERS reports will be obtained during active telephone follow-up with v-safe participants and will be processed, handled, stored, and accessed in accordance with existing approved VAERS procedures and policies.

Data from all components of v-safe, as well as VAERS reports obtained through the call center, may be combined into a master data set behind the CDC firewall using unique identification numbers assigned at registration.

Preapproved CDC investigators and data managers, including CDC contractors, will be the only individuals with access to the full data (v-safe, linked VAERS reports). All electronic documents, data sets, and files relevant to the project will be stored on network folders with restricted access on CDC computers. The v-safe team at CDC will be primarily responsible for data management activities, including data extraction, documentation, and archival of a final data set for data sharing purposes. The archive will include the protocol, statistical programs, human subjects review documents, statistical output, analytical data sets, and manuscripts. It will clearly identify the permanent storage location for these files.

A final data set at the end of the v-safe program with deidentified aggregate data will be made available for external data requests or through Freedom of Information Act (FOIA) requests.

Analysis plan

Descriptive analyses will be conducted using the data collected through surveys on a weekly basis during the surveillance period. Participation rates over time will also be calculated.

For v-safe participants who have a VAERS report submitted through the VAERS call center, additional analyses will be conducted. Rates of serious events as well as adverse events of special interest (AESI) following COVID-19 vaccination will be generated using VAERS reports solicited via v-safe to define the numerator and v-safe participants as the denominator (Attachment 2). VAERS reports that are considered serious or AESI will be reviewed by medical staff at CDC. Case definitions (Brighton Collaboration or other standard definitions as appropriate) will be applied to the AESIs. Reporting rates for each AESI will be calculated and compared to established background rates. If at any time rates observed in v-safe exceed what is expected from background rates, further investigation will occur within other vaccine safety monitoring systems, including VAERS and Vaccine Safety Datalink (7).

VAERS monitoring for all COVID-19 reports will include VAERS reports solicited from v-safe participants. Reports obtained from v-safe participants will be coded so that they can be distinguished from other VAERS reports and analyzed separately from other VAERS reports if needed.

Human subjects considerations and confidentiality

This protocol will require human subjects determination at CDC since CDC is the lead site and surveillance data will include collection of PII. No PII will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests. Participation is completely voluntary and individuals self-enroll. Participants can opt out of v-safe at any time and their data will be used for the time they were considered an active participant. As an analysis of data collected for non-research purposes, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare.

Duration

The anticipated duration of the v-safe program is approximately 6-8 months of active enrollment. The decision to discontinue v-safe or to modify v-safe procedures to scale back active telephone follow-up will be made in consultation with the CDC COVID-19 Vaccine Task Force leadership and FDA.

Limitations and challenges

Limitations and challenges for v-safe surveillance include:

- Enrollment and registration will initially be a manual process and will be dependent on healthcare providers sharing information about the system with vaccine recipients. Enrollment might be limited. While VAMS will help promote v-safe enrollment though automated text message reminders, not all jurisdictions will use VAMS, and VAMS text messaging capabilities may not be rolled out until several weeks/months after vaccine becomes available.

- Accurate capture of vaccine manufacturer information will depend on accurate self-report, at least initially. Vaccine recipients are expected to receive vaccination record cards specifying the vaccine they received, which might help to improve accuracy of these data.

- Vaccinated people who choose to participate in v-safe might be different from those who decline; therefore, rates of side effects and adverse events generated from v-safe might not be generalizable to the full population of vaccine recipients.

- V-safe allows people to enter late in the post-vaccination monitoring period. The group of individuals who enroll in v-safe late might be heterogenous–those who simply neglected to enroll early, those who chose to enroll only after experiencing a clinically important adverse event, and others. Data collected from these individuals may need to be analyzed separately from data from those who enrolled early.

- The information provided by v-safe participants at 3, 6, and 12 months after vaccination might be impacted by recall bias.

- Participants will likely be lost to follow-up at later time points, reducing participant numbers and likely creating biases in v-safe analyses of safety out to 12 months.

- Because v-safe relies on vaccine recipients reporting their own experiences after vaccination, v-safe is not conducive to capturing the adverse event of death following vaccination.

Dissemination

Data from v-safe will be important in the beginning phases of the COVID-19 vaccination program. Regular updates will be provided to advisory committees and data review groups. It is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports.

References

1. *The American Journal of Managed Care*. A Timeline of COVID-19 Developments in 2020. Available at https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020.

2. CDC. CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days.

3. Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach. *N Engl J Med* 2020; 383:1701–1703.

4. Su JR, Duffy J, Shimabukuro TT (2019). Chapter 1: Vaccine Safety. In Poland GA (Ed.) and Whitaker JA (Assoc. Ed.), *Vaccinations*. St. Louis, MO: Elsevier.

5. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

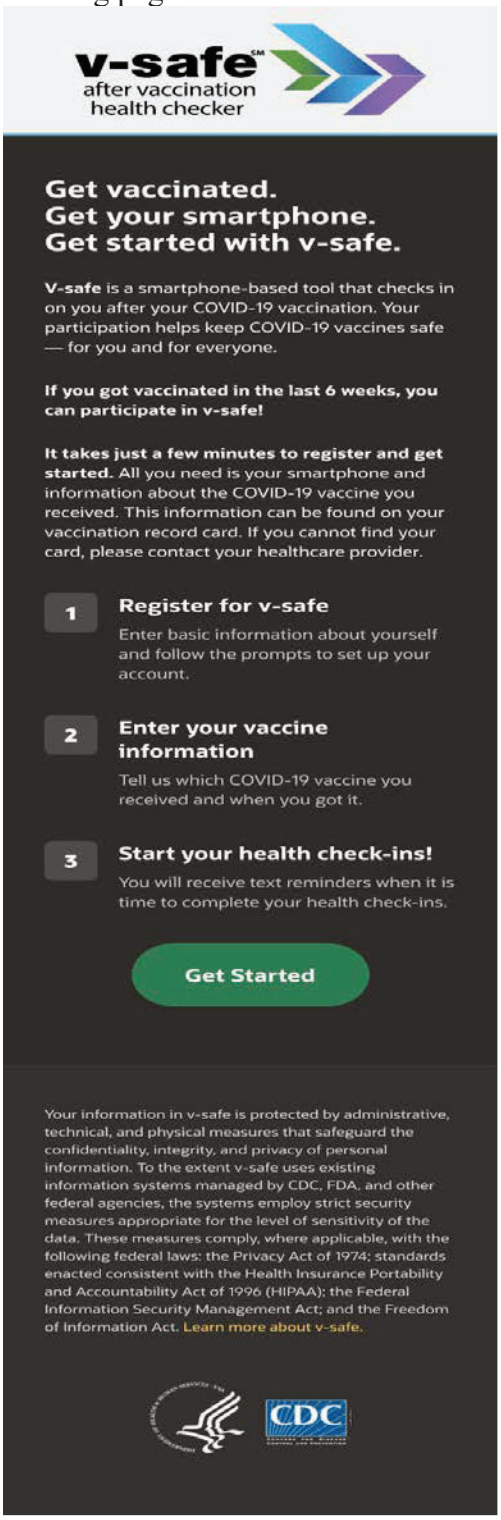
6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015; 33(36): 4398–4405.

7. *https://www.gsa.gov/technology/government-it-initiatives/fedramp)?*

8. McNeil MM, Gee J, Weintraub E, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine*. 2014; 32(42):5390–8.

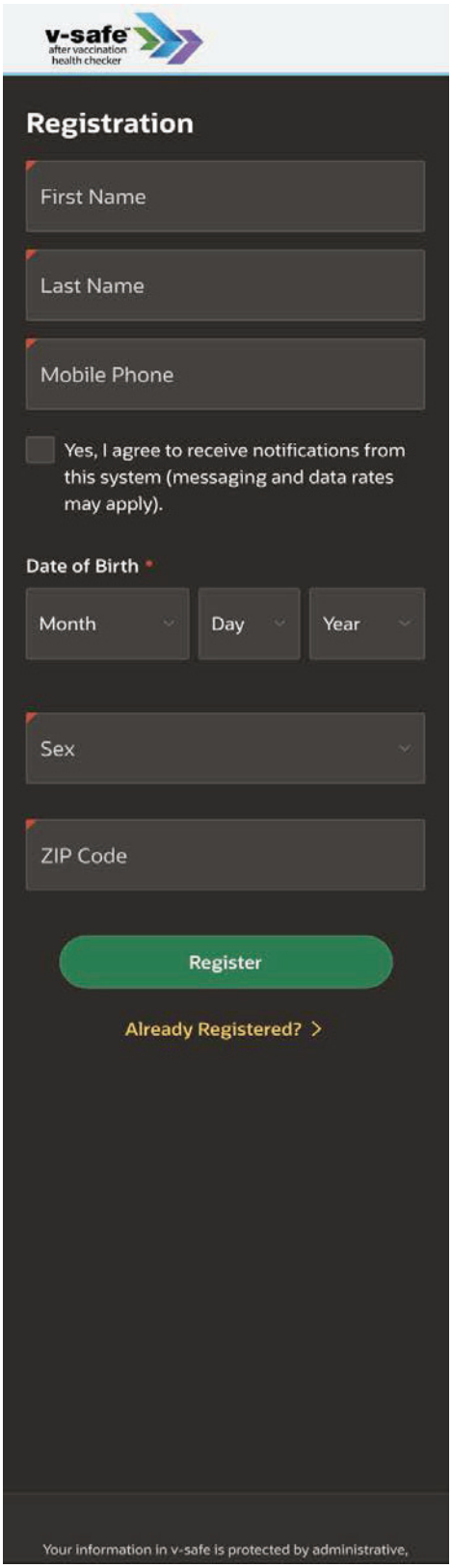
v-safe protocol: Nov 19, 2020

Attachment 1: V-safe survey script
Registration and my account:
Landing page:



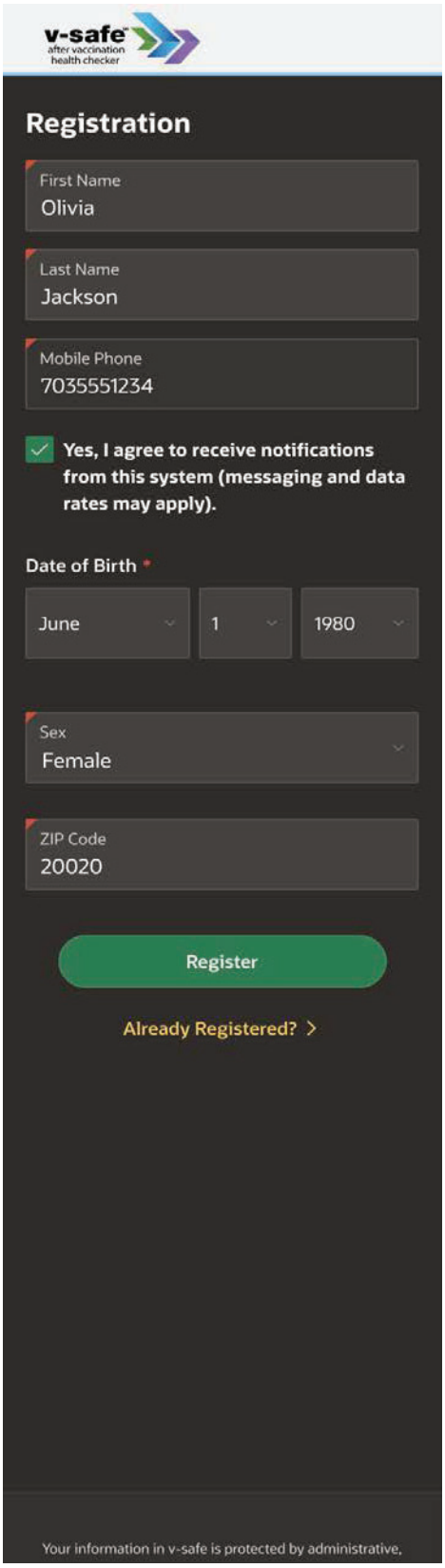
v-safe protocol: Nov 19, 2020

Registration page



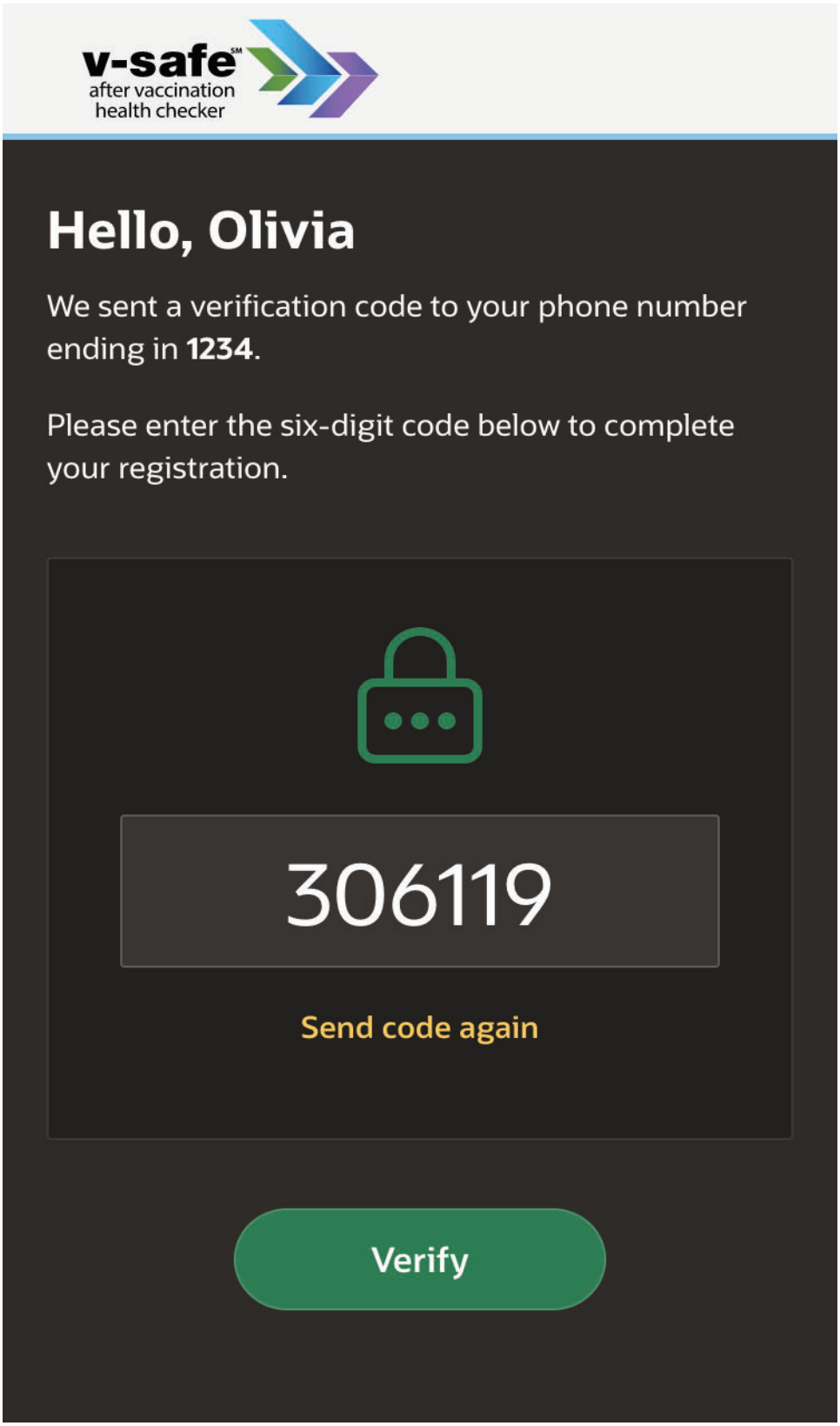
v-safe protocol: Nov 19, 2020

Registration completed:



v-safe protocol: Nov 19, 2020

Verification:



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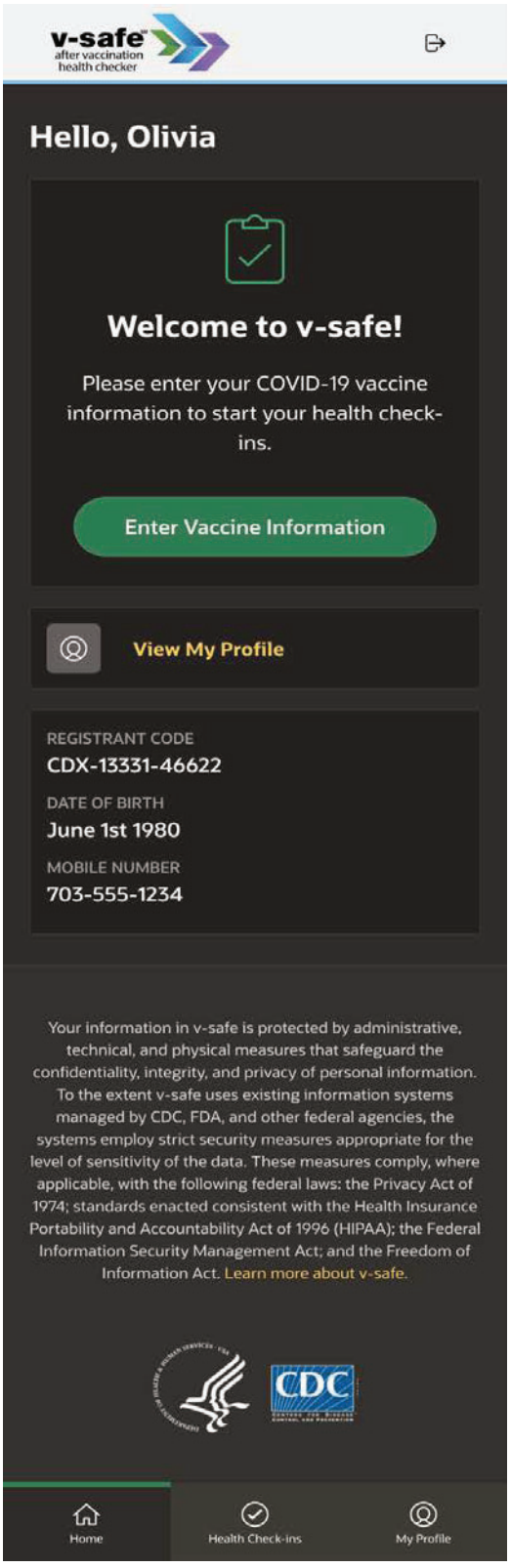
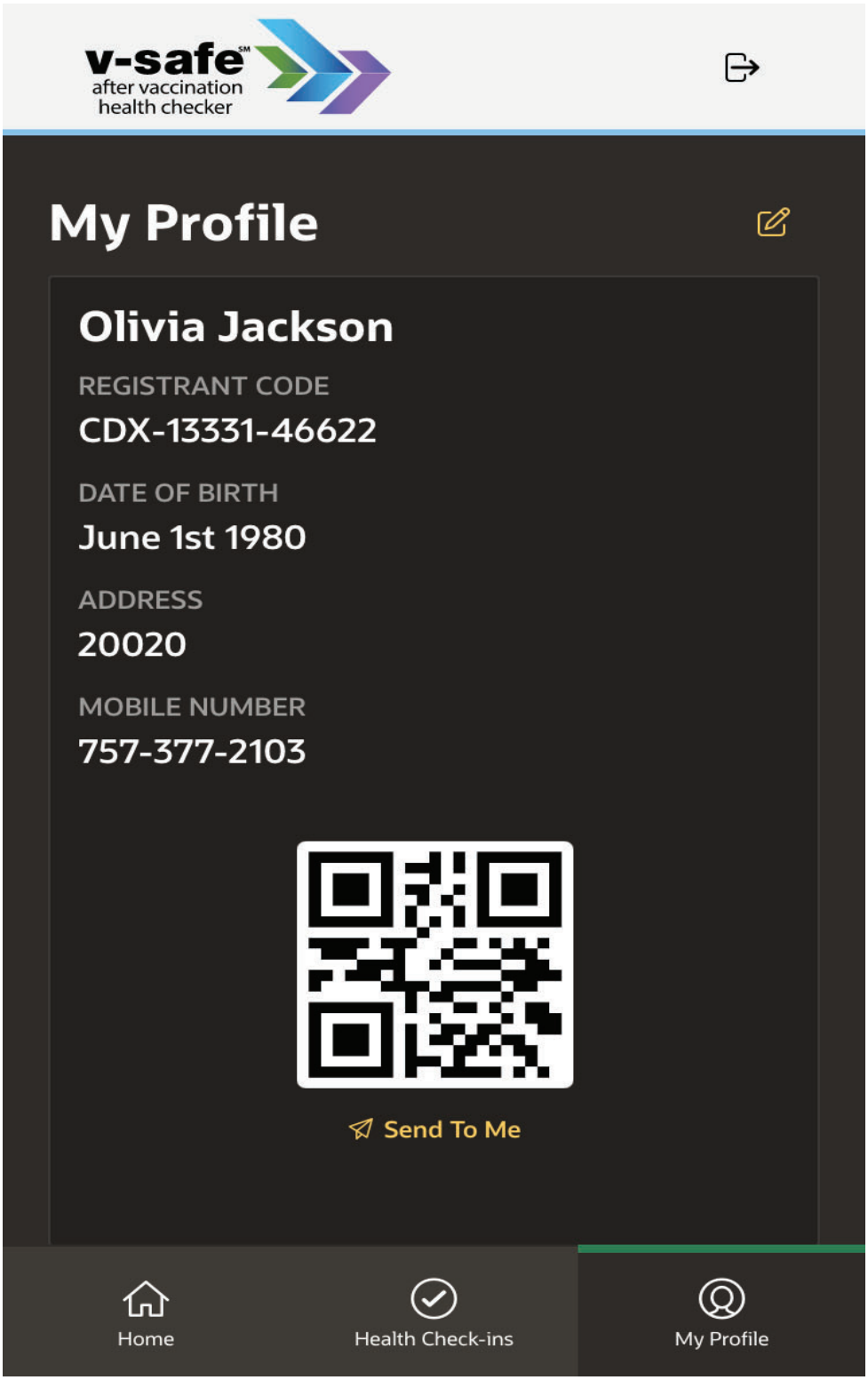
Account:



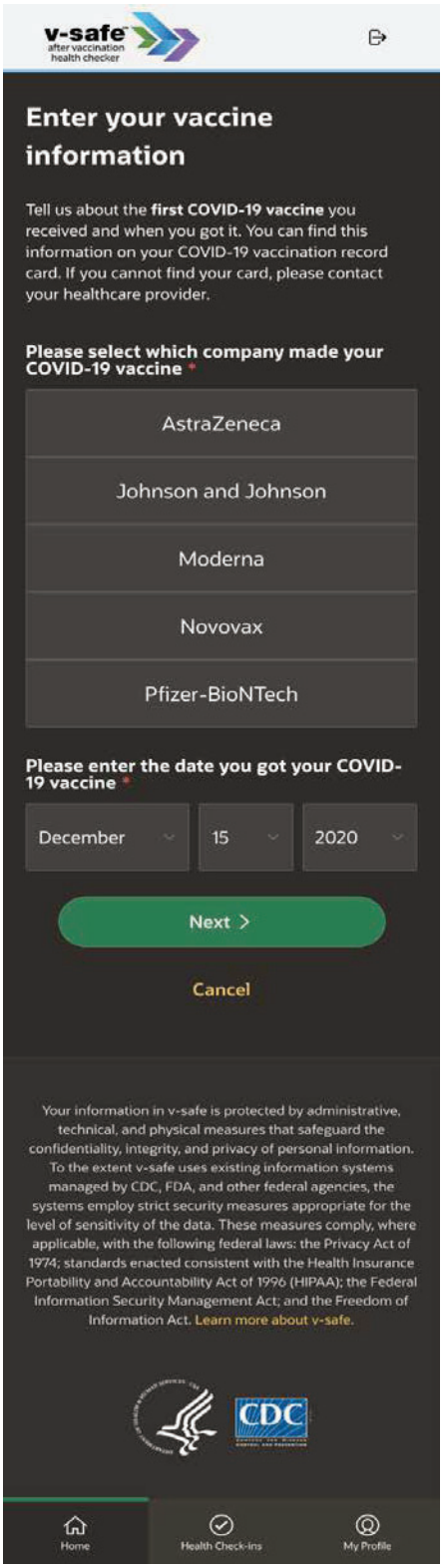
v-safe protocol: Nov 19, 2020

My profile:



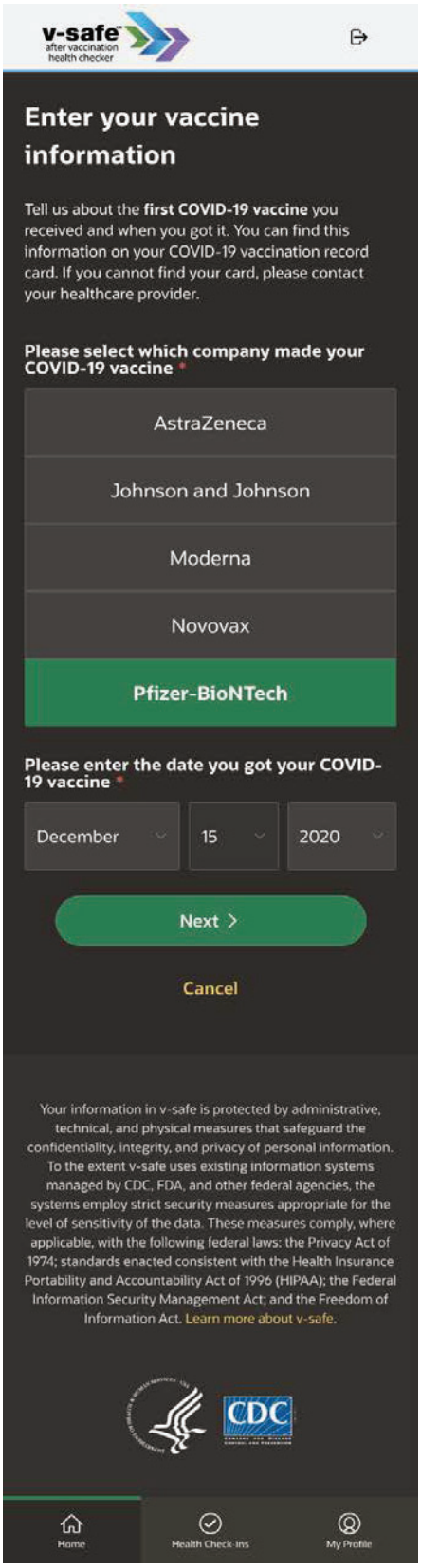
v-safe protocol: Nov 19, 2020

Enter vaccine:



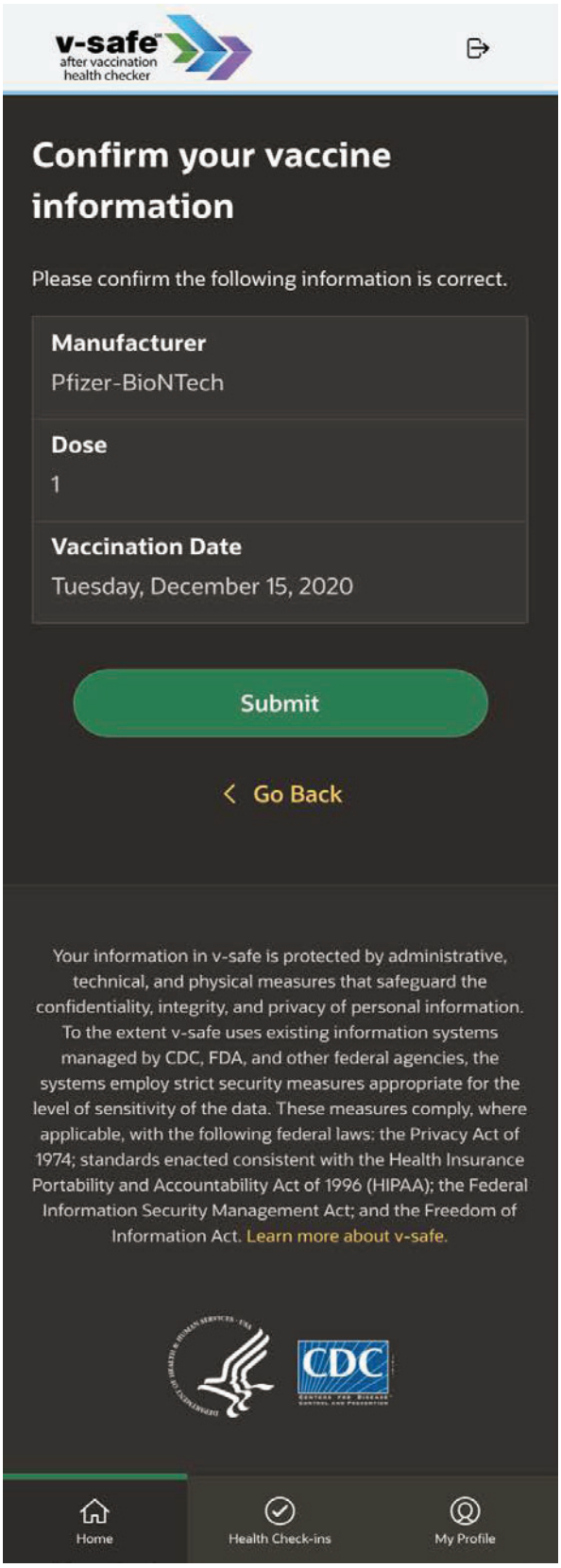
v-safe protocol: Nov 19, 2020

Enter vaccine- completed:



v-safe protocol: Nov 19, 2020

Confirm vaccine:



v-safe protocol: Nov 19, 2020

V-safe Dose 1 surveys through Day 42

DAY 0- Dose 1:

Text message invitation::
Hi <NAME>. It's time for your first v-safe check-in. (*link to personalized v-safe survey)*

Survey:
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your vaccination, have you had a fever or felt feverish?
☐ Yes ☐ No

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit): _____
Enter your highest temperature reading from today (degrees Celsius): _____

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site?
select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐None

How would you rate your symptoms:

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

Have you experienced any of these symptoms today?
Select all that apply.
☐ Chills

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☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site) ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the symptoms or health conditions you reported TODAY cause you to (select all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

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☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*

☐ ☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

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Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi, <name>. It's time for your daily v-safe check-in. (*link to personalized survey)*

Reminder text (for Day 7 survey only): Hi <name>, Please remember to do your daily v-safe check-in. ((*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site today?
Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

Have you experienced any of these symptoms today?
Select all that apply:
☐ Chills
☐ Headache

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☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Symptoms:
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limite your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site_ ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the symptoms or health conditions you reported today cause you to (Select all that apply):

☐ Be unable to work?
☐ Be unable to do your normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization

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☐ Other, describe:

_____

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

14 days (2 weeks) survey following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe:

_____

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

Alternate onscreen completion message FOR PFIZER and NOVOVAX RECIPIENTS:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

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21 days (3 weeks) following COVID-19 vaccination- DOSE 1:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For Pfizer/Novovax recipients:

Hi <name>.
Let's start today's health check-in.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.

(Survey will end and will be directed to enter Dose 2 information:)

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Moderna/AZ/Johnson & Johnson recipients & Pfizer/Novovax who did not get dose 2:

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check in, have you experienced any new or worsening symptoms or health conditions?
☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

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☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?
☐ Yes ☐ No

(If Yes) When were you diagnosed? _____ (mm/dd/yyyy)

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Moderna/AZ/:
Thanks for completing today's check-in.
Depending on your answers, someone from CDC may call you to check on you.
You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

28 days (4 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

For all Moderna, AZ and those Pfizer/Novovax who did not previously report Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2-dose vaccine recipients who report 'No' above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions:

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):
- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?

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☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

v-safe protocol: Nov 19, 2020

35 days (5 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Let's start today's health check-in .

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?
☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

v-safe protocol: Nov 19, 2020

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

42 days (6 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey)*
Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information

Thank you for letting us know that you received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization
☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

How would you describe your current state of health?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

How is your health now compared to your heath before your last COVID-19 vaccination?

☐ Better
☐ About the same
☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

☐ Yes
☐ No

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if this is the first survey then question below is not asked)*
☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?
(*This is only asked if participant answered above pregnancy question in a previous survey)*

v-safe protocol: Nov 19, 2020

☐ Yes
☐ No

Onscreen completion thank you message:
For all vaccine recipients at Day 42:
Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch

v-safe protocol: Nov 19, 2020

V-safe Dose 2 surveys through Day 42:

Dose 2

Day 0 post vaccination

Text Message after + 2nd vaccine info completed

Hi <NAME>. It's time to check-in with v-safe for your 2nd vaccine dose. (*link to personalized v-safe survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your second COVID-19 vaccination, have you had a fever or felt feverish?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Since your second COVID-19 vaccination, have you had any of these symptoms at or near the injection site?

Select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching

(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe

v-safe protocol: Nov 19, 2020

(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you experienced any of these symptoms today?
Select all that apply.
☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None
Any other symptoms or health conditions you want to report_____

Medical symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms cause some limitation of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible"
(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site) ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the symptoms or health conditions you reported TODAY cause you to (Select all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

v-safe protocol: Nov 19, 2020

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your answers, someone from CDC may call to check on you.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

v-safe protocol: Nov 19, 2020

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi <name>. It's time for your daily v-safe check-in. (*link to personalized survey)*

Reminder text (only sent for Day 7 survey, 3 days after original text sent): Hi <name>. Please remember to do your daily v-safe check-in. ((*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you had any of these symptoms at or near the injection site today?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

Have you experienced any of these symptoms today?

v-safe protocol: Nov 19, 2020

Select all that apply:

☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Medical symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms cause some limitation of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible"

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site_ ☐ Mild ☐ Moderate ☐ Severe

Health impact

Did any of the symptoms or health conditions you reported today cause you to (Select all that apply):

☐ Be unable to work?
☐ Be unable to do your normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit

v-safe protocol: Nov 19, 2020

☐ Hospitalization

☐ Other, describe:

_____

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

v-safe protocol: Nov 19, 2020

Weekly surveys: Days 14, 21, 28, 35– Dose 2

Text message and reminder:
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions:

(if Yes) "Did any of these symptoms or health conditions cause you to (check all that apply):"

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) "What type of healthcare visit did you have? (check all that apply)"

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

v-safe protocol: Nov 19, 2020

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

□ Yes □No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Were you pregnant at the time of your second COVID-19 vaccination? (*This is asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

42 days (6 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey)*
Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) "Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

How would you describe your current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
- ☐ No

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 2; if this is the first survey then question below is not asked)*
☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?
(*This is only asked if participant answered above pregnancy question in a previous survey)*

- ☐ Yes
- ☐ No

Onscreen completion thank you message:

Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch in a few months.

v-safe protocol: Nov 19, 2020

V-safe 3, 6 and 12 month surveys:

Monthly survey
Hi <name>.
Since we last contacted you, have you experienced any new symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐No

(if Yes) When were you diagnosed? _____(mm/dd/yyyy)_

Since your last check-in, have you had a home or laboratory pregnancy test that was positive?

☐ Yes
☐ No

v-safe protocol: Nov 19, 2020

How would you describe your current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your health now compared to your health before your last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your health problems might be related to your COVID-19 vaccination?

- ☐ Yes
- ☐ No

Onscreen completion thank you message:

3/6 Month:
Thanks for completing today's check in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, someone from CDC may call to check on you.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe.

12 Month:
Congratulations! You have completed your final v-safe check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Thank you for participating in v-safe! Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Take care and stay safe.

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

Attachment 6

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

CERTIFICATE OF FILING
OF

Freedom Coalition of Doctors for Choice
File Number: 804899545

The undersigned, as Secretary of State of Texas, hereby certifies that a Certificate of Formation for the above named Domestic Nonprofit Corporation has been received in this office and has been found to conform to the applicable provisions of law.

ACCORDINGLY, the undersigned, as Secretary of State, and by virtue of the authority vested in the secretary by law, hereby issues this certificate evidencing filing effective on the date shown below.

The issuance of this certificate does not authorize the use of a name in this state in violation of the rights of another under the federal Trademark Act of 1946, the Texas trademark law, the Assumed Business or Professional Name Act, or the common law.

Dated: 01/26/2023

Effective: 01/26/2023

Jane Nelson
Secretary of State

EXHIBIT H

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00117-A-PHS

April 3, 2023

Christopher Wiest
25 Town Center Boulevard, STE 104
Crestview Hills, Kentucky 41017
Via email: chris@wiestlaw.com

Dear Mr. Wiest:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted on behalf of the Freedom Coalition of Doctors for Choice to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on April 1, 2023. It challenges the Centers for Disease Control and Prevention (CDC) denial of your request for a fee waiver for initial request, 23-00462-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

EXHIBIT I

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00117-A-PHS

April 12, 2023

Chris Wiest, Esq.
25 Town Center Boulevard, Suite 104
Crestview Hills, Kentucky 41017
Sent via email: chris@cwiestlaw.com

Dear Mr. Wiest:

This responds to your Freedom of Information Act (FOIA) administrative appeal, which was received by the Office of the Secretary's Freedom of Information Act Office (OS FOIA) on April 3, 2023. On January 3, 2023, you submitted a FOIA request to the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) on behalf of the Freedom Coalition of Doctors for Choice. The request sought:

> All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).

As part of its request, Freedom Coalition requested that CDC waive any and all fees or charges. CDC/ATSDR assigned the request tracking number 23-00462-FOIA, but their initial response letter of January 4, 2023, stated that your request for a fee waiver had been denied. The agency sent you a final response to your request on January 12, 2023. No fees were assessed.

On March 31, 2023, you appealed CDC's denial of your client's request for a fee waiver. OS FOIA assigned your appeal tracking number 2023-00117-A-PHS.

CONCLUSION:

Even though the CDC did not grant the requested fee waiver, the significance is *de minimis* since no fees arose from the request. The subject appeal is hereby administratively closed as moot.

Alesia Y. Williams
Director, FOIA Appeals and Litigation
FOI/Privacy Acts Division

Copy to:
CDC/ATSDR FOIA Office

EXHIBIT J

From: Nelson, Jonathan (OS/ASPA) (CTR)
To: chris@cwiestlaw.com
Subject: PHS FOIA Response 2023-00117-A-PHS
Date: Wednesday, April 12, 2023 4:19:52 PM
Attachments: Wiest 2023-00117-A-PHS admin closure LETTER 20230412.pdf

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Dear Mr. Wiest:

Attached is the final response to FOIA appeal 2023-00117-A-PHS. If you have any questions regarding this matter, please reach out to me via email.

Please note that this final response does not affect the processing of appeal 2023-00067-A-PHS.

Sincerely,
Jonathan N. Nelson

To: chris@cwiestlaw.com
Sent: Friday, April 14, 2023 6:07 PM
Subject: Undeliverable: PHS FOIA Response 2023-00117-A-PHS

Delivery has failed to these recipients or groups:
chris@cwiestlaw.com
Your message wasn't delivered because, despite repeated attempts to contact it, the

recipient's email system didn't respond.
Contact the recipient by some other means (by phone, for example) and ask them to tell
their email admin that their email system isn't accepting connection requests from your
email system. It's likely that the recipient's email admin is the only one who can fix this
problem.
For more information, see Status code 4.4.7.

Diagnostic information for administrators:
Generating server: ainssmtp01.ains.com
chris@cwiestlaw.com
Remote server returned '554 4.4.7 < #4.4.7>'
Original message headers:
DKIM-Signature: v=1; a=rsa-sha256; c=relaxed/relaxed;
    s=Ainshhs; d=hhs.gov;
    h=mime-version:from:to:date:subject:content-type:message-id;
    bh=Rdn0+KnJFVRDvlFy6h1HLvC+4ePjm9fMsmb3/kyN5kA=;
    b=ySIBHizhA/1b2K1jn80VpPe9yd3MUHC27Z0IAu/cYbch0ccehVjmgwvcIpT09z
      fGGbQSf4wX72HhH3xk4vEwXwJmu/jKOh7RB9ODI1r6S7ZM1KgRDp+F3tkNJvs4
      JVw0CLuBldZU7Fc58dQJIvKX7byxPI/ukjca7OHjuL1iC94=
Received: from HHS-FXProd ([192.168.80.31]) by ainssmtp01.ains.com with
Microsoft SMTPSVC(7.0.6002.18264);
         Wed, 12 Apr 2023 16:16:20 -0400
MIME-Version: 1.0
From: <Jonathan.Nelson@hhs.gov>
To: <chris@cwiestlaw.com>
Date: Wed, 12 Apr 2023 16:16:19 -0400
Subject: PHS FOIA Response 2023-00117-A-PHS
Content-Type: multipart/mixed;
        boundary="--boundary_160_2cb7f61c-2e9d-4047-84b9-42cac7421ba3"
Return-Path: Jonathan.Nelson@hhs.gov
Message-ID: <FXSYNCCQiJNqJGcAkyg0004adf4@ainssmtp01.ains.com>
X-OriginalArrivalTime: 12 Apr 2023 20:16:20.0160 (UTC)
FILETIME=[A50C6C00:01D96D7B]

From: Nelson, Jonathan (OS/ASPA) (CTR)
To: chris@cwiestlaw.com
Subject: HHS/CDC FOIA Appeals 2023-00067-A-PHS and 2023-00117-A-PHS
Date: Monday, July 3, 2023 12:04:00 PM
Attachments: Wiest 2023-00067-A-PHS admin closure letter FINAL, 7.3.2023.pdf
PHS FOIA Response 2023-00117-A-PHS.msg
Undeliverable PHS FOIA Response 2023-00117-A-PHS.msg

Good afternoon, Mr. Wiest.

I learned this morning that you recently filed a lawsuit on behalf of the Freedom Coalition of Doctors for Choice with respect to CDC request 23-00462-FOIA, which spawned two administrative appeals. Although the lawsuit itself is still pending, both of your appeals are now administratively closed, albeit for different reasons.

Appeal 2023-00067-A-PHS was administratively closed today due to 45 CFR § 5.63, which requires that HHS stop processing an appeal when a lawsuit regarding the appeal has been filed. See attached .pdf letter.

Appeal 2023-00117-A-PHS, which addressed only the fee-waiver denial, was actually administratively closed on April 12. Because CDC assessed no fees for the initial request, your appeal was determined to be moot. Unfortunately, my email to you was marked as "undeliverable" and the email system's notification of this went to my junk mail folder instead of my primary inbox. In light of this, I am attaching a copy of my email from April 12 as well as the server's "undeliverable" email dated April 14. I apologize for not re-sending the admin closure letter to you sooner.

Please let me know if you have any questions.

Very respectfully,

Jonathan N. Nelson, Senior Analyst
U.S. Department of Health & Human Services
Office of the Assistant Secretary of Public Affairs
Freedom of Information and Privacy Acts Division